EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION,	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO PLAINTIFFS:	
Joplin, Deborah Lynn	2:12-cv-00787
Wheeler, Pamela Gray	2:12-cv-00455
Collins, Fran	2:12-cv-00931
Frye, Jackie	2:12-cv-01004
Bennett, Dina Sanders	2:12-cv-00497
Miracle, Charlene	2:12-cv-00510
Adams, Joan	2:12-cv-001203
Grabowski, Louise	2:12-cv-00683
Vignos-Ware, Barbara	2:12-cv-00761
Harter, Beth	12-cv-00737
Scholl, Sheri	12-cv-00738
Stubblefield, Margaret	12-cv-00842
Warmack, Roberta	12-cv-01150
Smith, Carrie	2:12-cv-00258
Thomas (Wyatt), Kimberly	2:12-cv-00499
Georgilakis, Teresa	2:12-cv-00829
Cone, Mary	2:12-cv-00261
Destefano-Raston, Dina	2:12-cv-01299
Hooper, Nancy	2:12-cv-00493
Lee, Alfreda	2:12-cv-01013
Reyes, Jennifer	2:12-cv-00939
Fisk, Paula	2:12-cv-00848
Sikes, Jennifer	2:12-cv-00501
Swint, Isabel	2:12-cv-00786
Teasley, Krystal	2:12-cv-00500
Thaman(Reeves), Susan	2:12-cv-00279
Warlick, Cathy	2:12-cv-00276
Sheperd, Donna	2:12-cv-00967

DEPOSITION OF JAIME SEPULVEDA, M.D.

Wednesday, March 30, 2016
8:12 a.m. - 4:33 p.m.
200 South Biscayne Blvd.
Miami Beach, Florida

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PROCEEDINGS

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Thereupon:

JAIME SEPULVEDA, M.D.,

having been first duly sworn, was examined and testified as follows:

THE WITNESS: I do.

DIRECT EXAMINATION

BY MR. DE LA CERDA:

Q. Okay. Doctor, could you please state your full name for the record?

A. Jaime L. Sepulveda.

Q. You're a urogynecologist hired by Johnson & Johnson and Ethicon, Inc. to provide opinions in support of TVT, TVT-O, Gynemesh, Prolift and Prosima; correct?

MR. SNELL: Form.

A. I have -- I have been subpoenaed to provide expert testimony about these products.

Q. (By Mr. De La Cerda) My name is Peter de al Cerda, I'm one of the attorneys who represents the plaintiffs' group.

Do you understand who I am and who I represent?

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A. Yes, I do.
Q. A couple of deposition rules. As we begin, first of all, we want to try to let each other finish, so allow my question to get out fully before you begin your answer and then I'll allow your answer to get out fully before I begin my next question. Is that fair?
A. Yes.
Q. And also when you're responding to questions, please do so verbally as opposed to an "uh-huh" or "uh-uh" or a head nod so it is clear on the record. Okay?
A. Yes.
Q. Also, if you don't understand my question, please ask me to repeat or rephrase it, otherwise, I'll assume that you understood my question. Is that fair?
A. Yes.
Q. And, of course, if you need a break at any time, please let me know and we'll take a break. The only thing is if there's a question pending, I ask the question be responded to before we take the break. Okay?
A. I -- I understand.
Q. All right. This is not the first deposition

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you've given; correct?
A. That's correct.
Q. What other depositions have you given?
A. I have given depositions on Garcia versus Ethicon.
Q. Okay. Anything else?
A. Yes, I have given deposition in local cases against a physician.
Q. Okay. So any other mesh cases where you've given a deposition other than Garcia?
A. Only Garcia.
Q. Okay. And then you've also given depositions, I guess, in medical malpractice cases?
A. Yes.
Q. Okay. How many of those have you given?
A. I have given two.
Q. Two. And have you acted as a treater or as an expert in those cases?
A. One was as a treater and the other one was as an expert.
Q. Okay. And when you acted as the expert, were you for the plaintiff or for the defense?
A. I was for the defense.
Q. And generally speaking, in the case where

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you were the treater, what type of case was that? I know it's medical malpractice, but what was the subject of that case?
A. That -- that was in 1994, a pelvic mass, specifically a sacral mass.
Q. Okay. And then how about the one where you acted as the expert for the defense?
A. It was a case of urinary incontinence after a vaginal delivery.
Q. And do you recall approximately when that one was?
A. That may have been three to four years ago.
Q. Did either of those cases involve Butler Snow?
A. No.
Q. Okay. And then in the Garcia versus Ethicon, you acted as an expert on behalf of Johnson & Johnson and Ethicon; correct?
A. That's correct.
Q. All right. Any other depos other than the ones you already mentioned?
A. No other depos.
Q. Okay. A few questions here. I assume the answers to these are all no, but have you ever had

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your privileges at a hospital revoked, suspended or limited in any way?
A. No.
Q. Have you ever personally been sued for medical malpractice?
A. Yes.
Q. Okay. And what was the subject of that particular case?
A. It -- it was, again, a chordoma, c-h-o-r-d-o-m-a, a chordoma, which is a tumor on the sacrum.
Q. I see. Okay.
A. And the other one was an injury to the ureter during the excision of a 20-centimeter pelvic mass.
Q. Okay. So these are two separate cases; correct?
A. Yes.
Q. In the first case that involved the chordoma, so you were the defendant in that case?
A. Yes.
Q. And was this the one from 1994?
A. Yes.
Q. Okay. So you actually gave a deposition in

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that case; right? Is that right?
A. Yes.
Q. And in the second case, the injury to ureter with the pelvic mass, did you end up not giving a deposition in that case?
A. There was no deposition.
Q. Okay. Without revealing -- I know settlements many times can be confidential. Without revealing any confidentiality, can you tell us anything about the resolution of those two cases?
A. They were both settled.
Q. Settled, okay.
Okay. So no trial; right?
A. There -- there was no trial and it was for a fully disclosed amount.
Q. Okay. Any other litigation against you other than those two cases that we talked about, any litigation of any type?
A. No.
Q. Have you ever had a disciplinary action against you by any medical board?
A. No.
Q. Have you ever been arrested or convicted of a crime?

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A. No.
Q. Okay. We discussed -- okay. Other than being retained in the Garcia case as an expert and in this -- in the case where you were retained as an expert that you mentioned before where you did a deposition, have you ever been retained as an expert in litigation, other than those two instances you've already mentioned?
MR. SNELL: Hold on, hold on. I'm going to instruct you. To the extent you have not been disclosed, you should be mindful of that and not identify those cases. To the extent you have not been disclosed, either by deposition, expert report, doing an IME of the plaintiff, under the rules, depending upon where you may have been retained, that is confidential information.
A. I gave testimony on Cavness.
Q. (By Mr. De La Cerda) Okay. Other than Cavness, Garcia and then this other case involving urinary incontinence after vaginal delivery, any other cases where you've been designated as an expert?
A. On -- on Ramirez.
Q. Right. Is there a name to the case where

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you were the expert for the defense on the urinary incontinence after the vaginal delivery? Do you remember a name?
A. I cannot recall.
Q. Okay. That would just make it easier to reference, but ...
Okay. In all four of these cases, the Cavness case, the Garcia case, the Ramirez case and the case involving urinary incontinence after vaginal delivery, all four of those cases you were retained by the defense; correct?
A. That's correct.
Q. You've never testified for the plaintiff as an expert; is that right?
A. I have not testified for the -- for a plaintiff. I have given opinions as part of the State of Florida Prosecution Unit, which is actually known as the Department of Health, Department of Health now. It's work that I have done for years for the Department of Health.
Q. Are these like criminal investigations into doctors or what -- what is it?
A. You know, that's why they eliminated the Prosecution Unit name because it sounds criminal, so

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now we all understand that it's -- it's any complaints that have been brought against a physician in my -- in my specialty, I and the board feels that needs to be reviewed, I review.
Q. Okay. And how long have you been doing that?
A. Close to 15 years.
Q. 15 years. Okay.
Let's talk briefly about your role as a consultant for Ethicon outside of litigation. Okay? So this word "litigation" is not contemplated, this is just your role as a consultant in what -- helping out what Ethicon does in its normal business. Okay?
So, first of all, in the past, you have been hired as a consultant for Ethicon; correct?
A. Yes.
Q. Okay. And do you recall when you were first hired as a consultant for Ethicon?
A. It may have been just after the year 2000, 2002. I don't recall the specific year.
Q. Okay. But early 2000s?
A. About -- about that time.
Q. Okay. And what was the purpose of you being hired on as a consultant when you first started?

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A. Initially, I was given the opportunity to -- to dissect cadavers and to put together the anatomy for the dissection in specimens as it would apply to the use of products.
Q. Okay. So I'm having a little trouble understanding what that might be. Explain to me what you would do, then, on a typical day involving that particular role.
A. It changed. It changed over the -- over the years. I started dissecting and teaching and being involved with my peers on how to use the different products and it was just an interest that I -- that I had very early in my career about surgical anatomy. So I just expanded that and I was given the opportunity while -- I was given instruments to work in the gallery.
Q. Okay. Did you have a title when you first began as a consultant for Ethicon?
A. No.
Q. Okay. Were there defined duties that you had when you first started out as a consultant?
MR. SNELL: Form.
A. No, nothing -- nothing that was defined as different task.

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Q. (By Mr. De La Cerda) Okay. They didn't have, like, a job description that was given to you when you first started?
A. No.
Q. Okay. And so in this role involving dissecting cadavers, where you were teaching other peers about how to use the Ethicon products, was that a role that remained consistent throughout your time as a consultant for Ethicon or did it change over time?
A. It changed based on the needs that they had, for what -- what they understood was my expertise.
Q. Okay. So let's do this. So the beginning is approximately the beginning of the 2000s. Has that con- -- has that role as a consultant for Ethicon ended or do you continue to be a consultant for Ethicon?
A. No, I don't consult with them anymore beyond the legal.
Q. And so when did your role as a consultant end?
A. Just -- just about the time that the products -- the prolapse products were decommercialized.

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Q. Okay. So is that 2012, approximately?
A. Yes.
Q. Okay. So I guess that's about ten years of acting as a consultant; is that fair?
A. Yes.
Q. Okay. So the manner in which your role as a consultant changed, was it really in -- in regard to the products themselves, what kind of product you were teaching, or is there some other way in which it changed?
A. It changed. It changed based on what -- whatever was understood that there was a need.
Q. Okay. Can you give me some examples?
A. Initially, it was seeing the products, how they would work, and nothing -- nothing in terms of experiment or research and development. It was more on how -- how to reproduce their use in the -- in the operating room.
Q. Mm-hmm.
A. And then I was able to -- to see -- to see how -- how the products were actually implemented in -- in the surgical environment. And there was a time in which I would just see other surgeons that were consultants. And then there was a time in which

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I would go to and meet with -- with a group at Ethicon and give a conference on anatomy or I would take them to the lab and show them the anatomy.
Q. Mm-hmm.
A. And then there was a time in which I actually wrote a manual of how to dissect -- dissect a specimen, make the best of that dissection.
Q. Okay. But tell me about this manual. What is it that you'd be dissecting -- so tell me, what was the content of this manual?
A. The labs -- the labs using specimens are very unique and they're very -- they're very expensive.
Q. Okay.
A. And the whole setup of getting a good specimen. And what we call "specimens" is a portion of a person and there -- there are certain things that we have to follow over the years, over the last 25 years that I have learned dissecting and understanding the anatomy. One of the most complex anatomies that you can have in any other -- other part of the body. So when we -- when we did this and there's -- my interest was that, and I verbalized that, that we could make the best use of these specimens in the lab.

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Q. Mm-hmm.
A. And not only that it would be -- it would be the best use, but also that it would be a systematic approach in the same way that first-year medical students are taught anatomy.
Q. Mm-hmm. Okay.
A. So to get -- to make that organized and to make that systematic and to make that consistent, then there was -- there was a proposal for a manual. That was just one part of -- of what could be done in -- in the lab- -- laboratory.
Q. And this was a manual that was done for Ethicon; right?
A. It was done for -- for them, but I think it was -- there were other -- other considerations beyond -- beyond anatomy and probably did not get developed, but I got the -- I got the opportunity to take my pictures and actually put it in -- on my thumb drive with presentations, which you're going to be requesting.
Q. Okay. Are these cadaver specimens, they're reused for purposes of teaching doctors how to do -- how to, for example, implant Ethicon's products; right?

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A. Well, cadavers are used in sections and, obviously, we're going to -- we're going to use a section that pertains to the procedure that we're doing and they -- they form the basis of teaching anatomy from the first year of medical school.
Q. Do they -- do the cadaver -- I guess the portions of the cadaver that are used to present how to implant products, do they eventually get used, to a certain extent, to where, okay, we can't use this cadaver anymore, like it's been used too much for this particular presentation?
A. You can -- you can always make -- make the best of what you're examining. So, yeah, if there is a portion that is used, you can always go to different things that you can teach from the -- from the cadaver. That's highly dependent on the condition of the cadaver.
Q. Yeah.
A. It's highly dependent on how it was prepared. It's highly dependent on how those individuals that are doing the dissection know how to do it.
Q. Okay. Okay. So going back to your role as a consultant for Ethicon and what it is that you did,

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have you now explained all the various things that you did as a consultant on behalf of Ethicon?
MR. SNELL: Form.
A. I -- I actually look at presentations. In addition to, I look at presentations. I would make a presentation to -- to different groups within Ethicon.
Q. (By Mr. De La Cerda) You would do presentations for other physicians about Ethicon's products; is that correct?
A. About Ethicon products and about the condition itself.
Q. Okay. And did the presentations that you do to other doctors for Ethicon include TVT, TVT-O, Gynemesh, Prolift and Prosima?
A. It was TVT-O, TVT-Secur, Gynemesh, Prosima, and Prolift.
Q. Any reason why you didn't do presentations on regular TVT or TVT-R?
A. I had a -- I had a preference for the transobturator slings.
Q. Had you used in the past a TVT Retropubic for your patients?
A. Yes.
Q. And why is it that you preferred the TVT-O

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over the TVT?
A. I felt I could do the same with less risk.
Q. And what risk are you specifically talking about?
A. Getting to the bladder. Very rare, but potential getting to the bowel and getting to a major blood vessel.
Q. You've testified before that you've made -- you've made about $100,000 a year as a consultant for Ethicon; is that right?
A. That -- I may have testified to that number, yes.
Q. Okay. And so if we're talking about ten years, we're talking about approximately a million dollars you made as a consultant for Ethicon; correct?
MR. SNELL: Form.
A. No, it doesn't -- doesn't get to that because it wasn't -- it wasn't like a salary. It was in a -- in a need and there were years that it was $3,000.
Q. (By Mr. De La Cerda) Do you have an approximation of how much you made total as a consultant for Ethicon?
A. I -- I think the largest and the best year,

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most active year, I may have done about 100. But that -- that's probably one or two years.
Q. Do you have a range, total, for all the years that you acted as a consultant for Ethicon?
A. Never -- never really counted.
Q. Do you have any documentation of that, of what the numbers might be?
A. My 1099s that I receive or my tax returns.
Q. Okay. And if Ethicon has records of that, you'd, of course, defer to whatever those records say; right?
MR. SNELL: Objection, form, foundation.
A. As -- as long as they correlate with my 1099.
Q. (By Mr. De La Cerda) Right. So if they had records of the 1099s, which I assume they do, you would defer to whatever those numbers are; right?
A. I -- I would defer to that.
Q. When you've presented on Ethicon's products, where have those presentations occurred, geographically?
A. You know, it happened mostly here either in Florida or in New Jersey. Occasionally, I would go

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to -- to other cities, Austin, Toronto, Dallas, Boston. Never -- never too -- never too far. I -- I made that decision that I wasn't going to go, let's say, to the Northwest or California maybe once because I have a practice that I have to take care of.
Q. Right. I guess you have the advantage, too, of being in Miami, doctors would want to come to you for the -- were there many presentations here in Miami, too?
A. There -- there were -- yeah, there were some in Miami, absolutely.
Q. Okay. When the presentations were out of town, Ethicon, of course, covered your -- your meals, your lodging, your transportation; right?
A. With- -- within the -- within the range that was specified for that kind of traveling.
Q. How was that done? How was the range specified?
A. We -- we were required to take a course on guidelines for -- as consultants for any kind of industry.
Q. Mm-hmm. And do you recall any of what those guidelines were?
A. I -- I do recall there was -- there were

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specifics on which hotel we could stay and -- and no first class traveling, and there was compensation, if we would drive, for the miles --
Q. Okay.
A. -- and there were also some -- some limits on what we could spend on food, although most of the time food was provided there.
Q. Do you know whether Ethicon believed you to be a good preceptor or teacher on its TVT products?
A. I -- I think that they visualized me as a good surgeon with good common surgical sense.
Q. And I just used the term "preceptor," I need to make sure that's understood. Could you explain to us what the term -- what your understanding of the term "preceptor" is?
A. The preceptor is -- is a term that was, I believe, from mostly the marketing people. I never really saw myself as a preceptor.
Q. Mm-hmm.
A. I saw myself as a surgeon. And if you ask any of my colleagues, they don't see me as a preceptor. Through the course -- through the years, I have seen doctors that have seen me for every single product and we always ended up talking about the same

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thing, the anatomy and the surgery.
Q. Mm-hmm. And so preceptor, I guess that's used as some version of saying that someone's a teacher; is that right?
A. I -- I think it was an internal term for -- for them, preceptor, and it's -- it doesn't get to the level of a teacher or a professor, it doesn't have that -- that responsibility. It doesn't have -- it has mostly the role of showing something, of demonstrating.
Q. Okay. Do you know whether Ethicon ever criticized the way in which you taught other physicians in preceptorships?
A. They -- they did not have a specific criticism and they -- they would ask, whenever they would bring someone to see me operating, that they had a -- that the doctors could get to see as much as they could see in terms of the variety of procedures, but, obviously, that -- the cases are what the cases are.
Q. Yeah.
A. You show what you have.
Q. Ethicon -- I guess, in other words, Ethicon never said -- made you personally aware of any specific criticisms of any type of the manner in which

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you were teaching other doctors how to perform these procedures; right?
MR. SNELL: Form.
A. There -- there was -- it was a relationship with -- with a lot of respect for what I did, for what I brought to the -- to their table.
Q. (By Mr. De La Cerda) Okay. So the answer is no, you never became aware of any criticisms; right?
A. No.
Q. In August of 2011, you decided to stop preceptorships due to the FDA situation; correct?
A. I -- I -- there was a communication that said we -- we need to look at this and we need to look at what the FDA is saying, and everybody needs to be on the same wavelength.
Q. Mm-hmm. And so what -- how long did that last, that decision to suspend or interrupt your preceptorships?
A. I don't -- I don't remember exactly how -- how long did it last or if I ever went back and did a consultation in other -- other regards. It's -- it was just a gen- -- probably a general concern from all sides.

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Q. Okay. Just to make sure. So you're unsure whether, in August of 2011 when you decided to stop the preceptorships due to the FDA concern, you're unsure whether you went back to consulting for Ethicon after that point?
A. Yeah, I --
MR. SNELL: Objection to form.
Go ahead.
A. -- I did -- I did not cut completely at that time and actually it was -- it was me relating, I believe, to Bob Zipfel, who was the professional education manager --
Q. (By Mr. De La Cerda) You said Bob Zipfel?
A. Zipfel, Z-i-p-f-e-l.
-- relating that we -- we need to get clear on the -- on the message and we need to include whatever is out there and be transpiring about it.
Q. And so what was it that you decided, along with Ethicon, to make clear about the message involving this issue?
MR. SNELL: Objection, form, Ethicon.
A. As far as I remember from my side, it was let's -- let's look at this. It was -- that's more of the attitude that I can recall.

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Q. (By Mr. De La Cerda) Do you remember ever discussing this FDA issue with doctors during a consultation on behalf of Ethicon?
A. I -- I don't remember that.
Q. Okay. Do you remember discussing this issue at all with any doctors in regard to Ethicon products?
MR. SNELL: Objection, form.
Go ahead.
A. I don't -- I don't remember specifics of talking to a specific doctor or being at a conference just talking about -- about this.
I don't even remember if it was 2007, 2008, or -- I don't remember which time frame it was. I am -- you know, I became aware of this, that I say at one point we need to stop or we need to review, we need to revise it, or we need to look at it, but it was never like, oh, no, I'm not teaching anymore, I'm not demonstrating anymore for you.
Q. (By Mr. De La Cerda) Mm-hmm.
A. That's what I can recall. That's the best of my recollection right now.
Q. Why is it important when the FDA puts out a warning, like they did in 2011, to investigate and look into what -- the reason behind the warning?

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MR. SNELL: Form.
A. It's because the results and the clinical experience that we're getting was different from what we were seeing in those -- in those reports.
Q. (By Mr. De La Cerda) Okay. So the FDA warning came out in July of 2011, was that a surprise to you?
A. It was -- it was a surprise in 2008 and it was in 2011. What I -- what I thought is evidence is going to come in and is going to show -- it's going to solve this difference that a group of doctors may have with other group of doctors.
Q. You're familiar with the Abbott study that came out -- it came out probably in 2014, I think. Abbott -- the lead author is Abbott, Mickey Karram is one of the authors as well. And one of the discussions they have is that many times when -- I think about half the time, at least -- when a patient has a complication involving a mesh implant, whether it be a sling or a pelvic organ prolapse mesh, they do not return to the physician that implanted it.
Are you aware of that phenomenon?
MR. SNELL: I'm going to object to the foundation on that.

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Go ahead.
A. I -- I've heard about that. I never believed that that's the case.
Q. (By Mr. De La Cerda) Okay. And why is that?
A. Because of my own experience, because of my -- the experience that I have heard from my colleagues. That's -- that's not what our experience is.
You -- you may have a small percentage that may not come back, but in my community, for example, we all know, we all communicate. There are four, five board-certified female pelvic medicine in the whole stretch all the way to Boca from here. We know each other and -- and the doctors also communicate with us, so there is a lot of communication there.
If there is a loss to follow up, it might be on the clinic setting, when you have these clinics, other -- other types of settings, but not in the private-practice setting.
Q. If a patient went to go receive treatment for a complication in a different city that's something like Dallas, for example, would you necessarily find out about that?

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A. I may not -- I may not find out, but I know that most of the time it's not even dependent on the patient. They -- they come and they communicate with me. I've had patients that have gone to New York, they come back and tell me this was my experience.
Q. You mentioned something interesting because you're -- and I hear this from physicians every time. I think this is our natural inclination.
You mentioned in your experience you haven't seen that happen. Ultimately, you would agree that your personal experience on that issue, on whether people come back to the primary physician or not, is, at best, only anecdotal. Do you agree with that?
A. It's -- it is definitely a portion that is anecdotal. I do talk to so many of my colleagues and if it's anecdotal, it repeats a lot.
Q. Yeah, I get that. I mean, here you are in a community where you do actually know all these physicians that do this thing and if the general consensus is that this is what's happening, it can certainly feel like this is the reality of it. But ultimately we've got a study that was done that looked at many people -- by the way -- strike that.
Are you familiar with this study, the Abbott

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study? Like have you actually reviewed it?
A. I -- I did not read that study complete, no.
Q. Okay. Then I'm going to move on to another subject then.
Going back to acting as a consultant, have you ever acted as a consultant for any other pharmaceutical or medical device company?
A. For pharmaceuticals, I work for ALZA Pharmaceuticals.
Q. Is that --
A. A-L-Z-A. When they came -- they came in with a new anticholinergic.
Q. I'm sorry, what is that?
A. ALZA, A-L-Z-A, Pharmaceuticals.
Q. And the drug?
A. It was Ditropan XL.
Q. Ditropan XL.
And what was that drug for?
A. For overactive bladder.
Q. How long did you work as a consultant for ALZA Pharmaceutical?
A. About two years.
Q. And do you recall approximately when that was?

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A. It was when I was starting the urogyne center here, so it may have been '96, '97.
Q. Any other medical device or pharmaceutical companies that you've acted as a consultant for, other than ALZA and Ethicon?
A. I -- oh, I worked for Ethicon on the laparoscopy area around 1994, internationally.
Q. Was that just for one year?
A. A year, year and a half, yes.
Q. Any other consulting work for pharmaceutical or medical device companies?
A. You know, I may have -- I may have had representatives from one or two companies that say I want you to go ahead and teach me how my product works and -- and teach me how -- how is it that urge incontinence is managed.
And I may say, okay, and some of them may give me a check, which I ended up either giving to the Residents Fund in Puerto Rico or did something with it, but it was something sporadic.
Q. Would these be some of the other mesh manufacturers, like Boston Scientific or American Medical Systems, companies like that?
A. No, I did not -- I -- I never did consulting

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for any other company on mesh but Ethicon.
Q. Do you remem- -- do you recall the names of the companies that you did this urge incontinence work for?
A. I think it may have been Detrol or --
Q. Detrol?
A. -- Enablex. I don't remember the name of the company.
Q. Okay. And do you recall the approximate years that would have happened?
A. No.
Q. Okay. Now let's get to the part that's always the most tedious. What is it that you brought here today with you?
A. I brought here in compliance with the papers served for the subpoena, I brought my CV --
You have a copy?
Q. Yes.
A. -- and a USB, in which I have any file that I had on my computer that when I -- when I was at Ethicon, I just downloaded my presentations.
Q. Okay.
A. And there were some videos of surgeries here.

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Q. Okay.
A. And I brought my biomechanics books and the book that Ethicon put together for -- about Gynemesh and Prolift, and I did -- the one on Gynemesh is about my slides.
And I -- but all the materials that were cited in my report and materials for prolapse, my materials for case specifics for tomorrow, depositions, and the Prolift monograph.
Q. Okay. And that's it?
A. I am missing the white paper on hydrodissection. That I could not find at all. I will make it my business to provide to you.
MR. SNELL: Peter, I think we provided -- there's thumb drives that my office did, too.
MR. DE LA CERDA: Are those all -- those are the case-specific ones?
MR. SNELL: Case and general.
Q (By Mr. De La Cerda) Okay. So that we're not taxing the court reporter too much on copying and the like -- first of all, are the materials that you brought, other than the books, are those all copies?
A. Yes.

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Q. Okay. What -- I guess what I would be most interested in is what you brought that is not on the Reliance List. Because most of -- just about everything on the Reliance List we can find.
And so, first of all, these book chapters, are those referenced in the Reliance List, these books that you have listed here in -- here in front of us?
A. No, they're not.
Q. Okay. So are there particular portions of those books that are relevant to your opinions or is it the whole book?
A. I -- I -- there are portions that are relevant to the way I see slings and meshes work.
Q. Okay. Okay. And can you tell us what -- is it a chapter? Is it a particular passage or --
A. They're -- they're chapters.
Q. Okay. And as far as you know, they are not referenced in the Reliance List at all?
A. They're -- they're not, that's why I brought them, and the same with the -- with the USB.
Q. Okay. So, again, first of all, let's do this. Let's separate out the items that are not on the Reliance List so we can make sure and mark and identify those and -- so let's do that.

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So the books that are here, these are the ones not on the Reliance List; right?
A. Yes, sir.
Q. And then you've got -- and I'm going to mark each of these in a second-- the USB that you brought; correct?
A. Yes.
Q. Okay. Anything else, other than those and other than the case-specific USBs that you brought, anything else that is not on the Reliance List?
A. The only one missing that I -- that I didn't bring today that I'm -- I made my best effort to bring you is the white paper that I wrote on hydrodissection along with Dr. Lucente and -- yeah.
MR. DE LA CERDA: Okay. So as far as marking these, anything -- any particular way you want to -- you want to do this, Burt?
MR. SNELL: It doesn't matter. This stuff here is like all general stuff, from his general reports and the Reliance List, and I think it's probably duplicative of the hard copies and also specific citations in the materials. I was just trying to sort out --
MR. DE LA CERDA: The case-specific --

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MR. SNELL: We sent so many cases to the thumb drives and stuff like that over time. This is general. If you want a copy -- I don't even know what's on these. I know they reproduced -- I think they were supposed to reproduce the materials list, but I haven't checked them to see.

MR. DE LA CERDA: Okay.

MR. SNELL: I mean, I agree, I think you ought to mark definitely the stuff that was just kind of general -- general impression, the general stuff that he brought.

MR. DE LA CERDA: Yeah.

MR. SNELL: And if you want to -- mark whatever you want, you know.

MR. DE LA CERDA: Yeah.

MR. SNELL: These just have his reports and, like he said, everything that he cited -- here's some articles in here. You can tell him, those are probably cited within there.

THE WITNESS: This is cited and this is cited, this is cited, too. This is a monograph. These two are new. These two are new.

MR. SNELL: Is there anything in this?

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Here.

THE WITNESS: This is not cited. Cited, cited.

MR. DE LA CERDA: I think we're going to have to do this the long way.

Q. (By Mr. De La Cerda) Okay. All right. So here's what I want to do. Just to make -- because I don't want to miss anything, because it looks like you might have some newer stuff. Maybe you looked at some additional research or something and found some newer stuff, but what I want to do is, let's just -- I want to stack it by category and then I'll mark each stack.

So the easiest way to do it, for me, at least, is do it by -- you know, we do ours like this, too. We're going to do it by stacks that involve certain subject matters, like, for example, everything you've brought today that is a medical literature, let's put that all into one stack and I'm going to mark that. Okay? And then everything you brought today that would be Ethicon documents, internal documents, we'll -- we'll mark that. And then everything you brought today that would be depositions or testimony that you reviewed and relied on, we'll

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mark that.

A. This -- this is all medical literature.

Q. Okay. So of the stuff that we've got here, what -- we have a stack here that's medical literature.

A. Yes.

Q. Are any of the binders medical literature?

A. All of it.

MR. SNELL: It's all literature. It's the stuff cited directly in his reports.

MR. DE LA CERDA: Okay.

MR. SNELL: Do you use footnotes or --

THE WITNESS: Yes, I did. Every footnote --

MR. SNELL: It should correspond in here.

MR. DE LA CERDA: And then this stack here that I've got is all not in the Reliance List; right?

MR. SNELL: I will say with the -- I'm about 99 percent sure that this would have been. The Prolift monograph, surgeons' monograph is definitely on his materials list and he's referenced that before. This is his actual -- this is your actual preceptor book. I don't know what you called it.

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THE WITNESS: It's the book that Ethicon made on Gynemesh and Prolift and they -- and I put together the first one.

MR. SNELL: I think that that's on his materials list, too, but just in case, I mean he brought that. That's his actual one.

The Surgeons' Resource Monograph, I know for a fact, has got to be on there.

MR. DE LA CERDA: So what I'm going to do is --

MR. SNELL: He brought that. That's obviously his originals.

Q. (By Mr. De La Cerda) I'm not going to mark these, I'm just going to identify them.

So today you brought with you the Gynecare Prolift and the Gynecare Gynemesh Preceptor Presentation Kit; correct?

A. Yes.

Q. And these are your -- this is your original?

A. Yes.

Q. Now, do you have this available at all electronically?

A. No.

MR. DE LA CERDA: Okay. Do you know if

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these are available electronically?
THE WITNESS: There might be a CD.
MR. SNELL: I think if you open the inside cover, there are CDs.
THE WITNESS: There might be a CD there, yes.
MR. DE LA CERDA: Because what I would like to do is get a copy of this, just electronically, because this -- so it's not copied -- so the court reporter doesn't have to copy it.
So how do you want to do that?
MR. SNELL: Do you want -- can I take it?
THE WITNESS: Yeah. Send it back because it's the only one I have.
MR. SNELL: I mean, there's two ways. We can either have the court reporter do it and then it's going through multiple people's hands or if you give it to me, I'll make color copies of everything, the cover, the back, the pages, and then I'll burn the CDs.
MR. DE LA CERDA: Okay.
MR. SNELL: I'll basically give you an exact copy of what you're holding and then I'll actually make a copy for myself, because I don't

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have a copy of that exact one, and then I'll give it back to the doctor.
MR. DE LA CERDA: Okay. So then that --
MR. SNELL: Let's make a record for that, a note for that.
MR. DE LA CERDA: So for the record, then, that will be Exhibit 1. I'm just going to put this here for now.
MR. SNELL: I will make a note I need to take that and copy it.
MR. DE LA CERDA: So for the record, Exhibit 1 is the Gynecare Prolift and Gynecare Gynemesh PS Preceptor Presentation Kit.
(Plaintiff's Exhibit No. 1 was marked for identification.)
MR. DE LA CERDA: Exhibit 2 is going to be Dr. Sepulveda's original Prolift Surgeon's Resource Monograph.
(Plaintiff's Exhibit No. 2 was marked for identification.)
Q. (By Mr. De La Cerda) Now, Exhibit 3, I'm going to mark, these are -- this is medical literature that you've gathered, Dr. Sepulveda; correct?

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A. Yes.
Q. And this is medical literature that happens not to be on the Reliance List; correct?
A. That's correct.
MR. DE LA CERDA: So I'm marking that as Exhibit 3.
(Plaintiff's Exhibit No. 3 was marked for identification.)
MR. SNELL: Just for the record, since, obviously, my firm was the one who made the Reliance List, I do believe that one of those may be on there.
MR. DE LA CERDA: Okay.
MR. SNELL: Like the ACOG committee opinion on vaginal prolapse mesh, I'm pretty sure that's on the materials list, if I even have his materials list.
You can keep doing that.
MR. DE LA CERDA: Okay.
MR. SNELL: But I'm pretty sure that would have been sent.
MR. DE LA CERDA: Prosima IFU, I'm sure that was on the Reliance List.
MR. SNELL: All that stuff is on the

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Reliance List.
THE WITNESS: I can take that back.
MR. SNELL: All the professional education slides, those are on there.
Q. (By Mr. De La Cerda) All of these are also on the Reliance List; right? Okay. So I'm not going to mark those.
And then, now, books. Let's go through each of these.
First of all, I'm looking at a book called "Biomechanics: Mechanical Properties of Living Tissues," the Second Edition, published by Springer and the author is Y.C. Fung, F-u-n-g.
Do you have specific chapters that you can identify within this book that you rely on?
A. Yes. Chapter 7.
Q. Okay. Any others?
A. No, 7.
MR. DE LA CERDA: Okay. So I'm going to mark this book as Exhibit 4 and then if we can just get a copy of chapter 7, just chapter 7, then the book can be returned.

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(Plaintiff's Exhibit No. 4 was marked for identification.)

Q. (By Mr. De La Cerda) You've also brought a book entitled "Introductory Biomechanics From Cells to Organisms." The author is -- or authors are C. Ross Ethier, E-t-h-i-e-r, and Craig A. Simmons. It looks like this is published by Cambridge University Press.

Are there any chapters or passages within this book --

A. Yes.

Q. -- that supports your opinions?

A. Chapter 9.

Q. Okay. Great. I'll mark this book, "Introductory Biomechanics," as Exhibit 5 and then we'll just get a copy of that particular chapter you referenced, chapter 9.

(Plaintiff's Exhibit No. 5 was marked for identification.)

MR. DE LA CERDA: Another book you brought is called "Biomaterials and Biomedical Engineering" published by Trans, T-r-a-n-s, Tech, T-e-c-h, Publications. This one is edited by W. Ahmed, A-h-m-e-d, N. Ali, A-l-i, and A. Öchsner.

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It's O-umlaut-c-h-s-n-e-r.

And I'm marking this book as Exhibit 6.

(Plaintiff's Exhibit No. 6 was marked for identification.)

Q. (By Mr. De La Cerda) Are there any chapters or passages in that book that you rely on?

A. Yes.

Q. What are they?

A. Chapter 12.

Q. Okay. Thank you. And then we'll get a copy of that and return the original book to you.

Okay. Now, you've also -- the other material other than the case-specific materials, the other material -- materials you've brought with you have all been cited either in your report or in your Reliance List; correct?

A. That's correct.

Q. Okay. Great. Now the last thing I'm going to do --

MR. SNELL: Peter, one thing --

MR. DE LA CERDA: Yes.

MR. SNELL: -- for clarification. I had mentioned I thought the ACOG physician statement from 2011 on transvaginal POP mesh was in. It's

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on his materials list. For some reason these don't have page numbers, but it's under "other materials."

MR. DE LA CERDA: Okay.

MR. SNELL: I put a check next to it.

MR. DE LA CERDA: Okay. Great. All right.

Q. (By Mr. De La Cerda) Now, the last bit of materials that you brought with you are various thumb drives. What are these thumb drives?

A. These are the thumb drives that have the articles that you see in these binders.

Q. Oh, I see. Okay. So actually, it would be nice to go ahead and mark these. So we have four different thumb drives. Each of these thumb drives is actually labeled with a product, as well. So there is Sepulveda TVT - TVT-O, Sepulveda TVT-S, Sepulveda Prolift, and then there's another Sepulveda TVT-S, I don't know if that's just a repeat, but I'll mark each of these with its own sticker. We're on 6.

So I'm marking as Exhibit 7 to your deposition the thumb drive that has Sepulveda TVT and TVT-O and this thumb drive contains reliance materials and materials cited in your report; correct?

A. Yes.

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(Plaintiff's Exhibit No. 7 was marked for identification.)

Q (By Mr. De La Cerda) Then I'm marking as Exhibit 8, Sepulveda TVT-S, and these are also documents referenced in your Reliance List and your report relating to TVT-S; correct?

A. Yes.

(Plaintiff's Exhibit No. 8 was marked for identification.)

Q (By Mr. De La Cerda) Then I'm marking as Exhibit 9 to your deposition the thumb drive that has -- that's marked Sepulveda Prolift, and these are materials referenced in your Reliance List and your report for Prolift; correct?

A. Yes.

(Plaintiff's Exhibit No. 9 was marked for identification.)

MR. DE LA CERDA: Do you know why there is a second TVT-S one?

MR. SNELL: I have no idea.

MR. DE LA CERDA: I'll just mark it as another one.

MR. SNELL: Somebody might have just made two copies. I can open it up and look at it real

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quick.
MR. DE LA CERDA: I'll just mark it.
Then I'm also marking as Exhibit 10 to your deposition a second thumb drive labeled "Sepulveda TVT-S," which I assume is also reliance materials and documents referenced within your report; correct?
A. Yes.
(Plaintiff's Exhibit No. 10 was marked for identification.)
MR. DE LA CERDA: Case-specific, they can deal with that.
THE WITNESS: I need to -- to -- I did not remember seeing the Bianchi-Ferraro --
THE COURT REPORTER: I'm sorry, the --
THE WITNESS: I do not remember seeing the Bianchi-Ferraro paper on TVT-Secur and TVT-O.
MR. SNELL: Is it in this pile?
THE WITNESS: I want to double-check that because I --
MR. SNELL: Bianchi-Ferraro?
THE WITNESS: Bianchi-Ferraro, which I referred to in the Garcia deposition.
MR. SNELL: Okay. This is other literature.

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You want to give that to him. That's additional.
THE WITNESS: Additional.
MR. DE LA CERDA: Oh, okay. All right. I'm also marking as Exhibit 11 medical literature that you've handed to me.
(Plaintiff's Exhibit No. 11 was marked for identification.)
Q (By Mr. De La Cerda) What is this medical literature?
A. That is -- this is medical literature about the -- one case report of clear cell carcinoma of the vagina and there's -- in a patient that has had a midurethral sling. This is the response to that article.
Q. (By Mr. De La Cerda) Okay. So this is all within Exhibit 11. So the second article within Exhibit 11 is?
A. The response to this article.
Q. Okay. And the third article within Exhibit 11?
A. This is vaginal -- these are different papers, but they're not directly related to this one.
Q. That's okay. So these are all -- I guess just to make sure just for purposes of the record,

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Exhibit 11 contains additional medical literature that you're relying on for your opinions; is that right?
A. Yes.
Q. Okay. We'll just leave it at that and then, of course, if you need to refer to any of it during your deposition --
A. And this is the paper that I was just referring about the Bianchi-Ferraro on TVT-O and TVT-S.
MR. DE LA CERDA: Okay. So I'll mark this one separately as Exhibit 12.
MR. SNELL: Is that one in your report, do you know?
THE WITNESS: No, but I refer to it on the Garcia deposition.
(Plaintiff's Exhibit No. 12 was marked for identification.)
MR. DE LA CERDA: For purposes of the record, Exhibit 12 is a article entitled "Randomized controlled trial comparing TVT-O and TVT-S for the treatment of stress urinary incontinence: 2-year results."
Is it okay if I clip --
A. Yes.

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Q. (By Mr. De La Cerda) Just for now, and then if you need to look at them, of course.
A. And I gave you a copy of my CV --
Q. Yes.
A. -- without my home address.
Q. Okay. I've got one here and if you like, I can use this one for the record.
A. Yes, I just made it available to you in case ...
MR. SNELL: Is that the same thing?
THE WITNESS: Yes, that's the one. The Bianchi-Ferraro has been referred already on this.
MR. SNELL: Footnote 117.
Q. (By Mr. De La Cerda) Okay. What I'm going to do is I'm going to mark as Exhibit 13 to your deposition your CV.
(Plaintiff's Exhibit No. 13 was marked for identification.)
Q (By Mr. De La Cerda) So I'm marking as Exhibit 13, that's your -- is that your current curriculum vitae?
A. Yes.
Q. And is that, to the best of your knowledge,

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current?
A. It is -- it is current.
Q. Okay. Anything else -- anything on it that you know of that needs to be updated, corrected, edited, anything like that?
A. On my report that I'm the principal investigator at the Fibroid Registry research project, that project was completed and closed.
Q. Okay. And is that the only thing on your CV that you know of that would need to be corrected?
A. It was the only research project that was open.
(Plaintiff's Exhibit No. 14 was marked for identification.)
Q. (By Mr. De La Cerda) Okay. I'm also marking as Exhibit 14 to your deposition your Reliance List for the general report.
This is what I've received as your Reliance List. Does that appear to be a true and correct copy of it?
MR. SNELL: Is this Exhibit 14?
MR. DE LA CERDA: Yeah.
A. I don't see any discrepancies overall in this list from what I have here.

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Q. (By Mr. De La Cerda) Okay. Great. Now I'm going to show you what I've marked as Exhibit 15 to your deposition.
(Plaintiff's Exhibit No. 15 was marked for identification.)
Q. (By Mr. De La Cerda) Does this appear to be a true and correct copy of your expert report, your general expert report, on Gynemesh, Prolift and Prosima?
A. This is accurate and correct.
(Plaintiff's Exhibit No. 16 was marked for identification.)
Q (By Mr. De La Cerda) Okay. And now I'm showing you what I've marked as Exhibit 16 to your deposition. Does this appear to be a true and correct copy of your general expert report on TVT and TVT-O?
A. It is a correct copy.
MR. DE LA CERDA: We've been going now for about an hour. Are you okay to continue or do you want to take a break?
THE WITNESS: Let's take a bladder break and we'll come back in five.
MR. DE LA CERDA: Sounds good.

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(Thereupon, a recess was taken from 9:24 a.m. until 9:26 a.m., after which the following proceedings were held:)
Q. (By Mr. De La Cerda) All right. Doctor, we're back on the record.
When -- when was it that you were first contacted regarding the general opinions that you have as to these products that we're here today for?
A. For -- for the -- for the MDL, around September. We spoke around September.
Q. September --
A. Last year.
Q. -- of last year, 2015?
A. Yes.
Q. And do you recall who you talked to first?
A. I -- I spoke to Burt.
Q. Okay. And was the topic discussed that you would be providing general opinions as to these specific products: TVT, TVT-O, Prosima, Prolift and Gynemesh?
A. That's correct.
Q. And what was the scope of your assignment for this particular -- for your opinions in this case, to your understanding?

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A. Yes, I understand the scope is to -- to review the literature and -- and go over things that I have read for -- throughout the years.
Q. Were there certain things that you were to focus on within the context of your opinions?
A. The --
THE COURT REPORTER: I'm sorry, did you --
MR. SNELL: Objection, form. I just say "form," but that means objection, form. I try to cut down your typing on the record.
A. The randomized controlled trials concentrate in the evidence.
Q. (By Mr. De La Cerda) What about internal documents, was there any focus that you were to place on the substance or the significance of Ethicon's internal documents in forming your opinions?
A. No. It's -- I have received -- just to be accurate in my response, I received, probably a year ago, internal documents, but not as part of this.
Q. Okay. So your focus really was and your opinions here was to provide those opinions based on literature as opposed to what was found in the internal documents; is that fair?

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MR. SNELL: Form.
A. Based on the -- on the evidence, on the scientific evidence.
Q. (By Mr. De La Cerda) As opposed to the internal documents; right?
A. The internal documents are not -- are not included on -- on this review or -- because it's a scientific review.
Q. I guess you haven't completed all -- well, let me just ask.
Have you completed all of your work on this case?
A. Yes. So far from my Reliance List and this is -- this is the product.
Q. Do you currently have any further work planned?
A. As -- as information may be required, I'll -- I'll review the papers, I'll review scientific literature, and everything that is coming up.
Q. So -- but as far as anything specific planned, is there any additional -- is there any additional task that you have planned? Other than, you know, tomorrow we have depositions for the case-specific, but other than the depositions coming

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up tomorrow, are there any specific tasks that you have planned relating to your opinions in this case?
A. No, this is -- this is my -- my product.
MR. SNELL: I'll make a note for the record. As plaintiff's experts' depositions are coming in, I know there are still depositions going on today, tomorrow, we'll send those to him, and if he has commentary or his opinions are changed, then, obviously, I'll let you know.
Q. (By Mr. De La Cerda) How much have you billed thus far for your general opinions involving TVT, TVT-O, Prosima, Prolift and Gynemesh?
A. I have -- I have copies of the invoices that I have submitted.
Is it okay if he has other -- other hours from another case, or should I just say the number of hours?
MR. SNELL: Let me see what you're talking about. The invoices -- let me look at them real quick.
MR. DE LA CERDA: Do you want to go off the record for a second? Let's go off the record.
(Discussion held off the record.)
(Mr. Sparks entered the room.)

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A. I can make copies again of it, but I did prepare your invoices. My invoices to -- I put it in a folder, they were neatly organized, the hours. I -- I just cannot find it, honestly cannot find it.
Q. (By Mr. De La Cerda) Okay. So what we'll do is when you do find it, you'll agree to provide that to us?
A. Absolutely.
Q. Okay. And so --
MR. SNELL: Why don't we save an exhibit number on the record, and I'll produce that, but I think he probably has a good idea as to how many hours he spent.
MR. DE LA CERDA: Okay. So what I'm going to do is, I'm reserving Exhibit 17 for the invoices that Dr. Sepulveda has prepared reflecting his work and his opinions for this case.
(Plaintiff's Exhibit No. 17 was marked for identification.)
Q. (By Mr. De La Cerda) First of all, do you have an idea of approximately how many hours you've spent preparing your opinions?
A. It's -- an approximate is about 120 hours.

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Q. And your report mentions that you bill at $500 an hour; right?
A. Yes.
Q. And so was it -- was that rate the same for all 120 hours that you performed --
A. Yes.
Q. And was -- do you know whether your invoice, did it break down the tasks that you were performing, did it break it down by product?
A. No, it's all MDL.
Q. Okay. Was it broken down by, for example, reviewing documents, meeting -- meetings with defense counsel, deposition time? Was it broken down in any way like that?
A. No, it's just for MDL, all the time that I've spent in putting -- putting together -- putting the reports together, putting -- for all the different products all into one MDL.
Q. Okay. So one block bill of 120 hours --
A. Right.
Q. -- approximately?
A. That's correct. Around -- approximately.
Q. Okay. Now, the types of tasks you would perform in developing your opinions, what did those

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include?
A. I have to write the report, I have to proofread -- proofread it, and I update it with the -- with the Reliance List. I -- I do research and whatever papers I -- I find that are relevant, I just submit it and it gets added to the Reliance List.
Q. Okay.
A. I also -- I review the case specifics and that included seven -- seven cases in which -- in which depositions and medical records and summaries were reviewed.
Q. Okay.
A. And then the time, getting together, getting prepared for this.
Q. Anything else that you can think of?
A. That would be at a later time because we got ready yesterday and the time today.
Q. Let's talk a little about what you just mentioned. Does the 120 -- approximately 120 hours that you mentioned, does that include all of your work for the case-specific?
A. Yes.
Q. Okay. Do you know approximately how much you spent -- how much time you spent as to each

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case-specific report that you prepared?
A. I -- I probably spend about, just -- just a rough, rough estimate, it's ten hours per each one, each one of them.
Q. And do you know how many case-specific reports you prepared?
A. Seven.
Q. Seven. Okay. I know these are rough numbers here, but so seven case-specific reports at about ten hours a piece, it's about 70 hours. So the balance, the rest of that, would that be dedicated towards your general opinions as to the products involved here?
A. Yes.
Q. Okay. And you mentioned preparation for your deposition. When is it that you prepared for your deposition today?
A. Yesterday.
Q. And how long did you prepare?
A. We -- we spend eight, ten hours.
Q. And that's eight to ten hours that you spent with Burt Snell?
A. Yes.
Q. Counsel for Ethicon; right?

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A. Yes.
Q. Anybody else?
A. No.
Q. In your deposition preparation, you reviewed documents; is that right?
A. Yes.
Q. Okay. Are those the documents that we have here that we've marked today?
A. Yes.
Q. Okay.
A. And -- yeah, all this has been marked.
Q. Do you have any rough estimate of how much more you anticipate billing before trial?
A. I -- I don't know when it's going to trial. It's -- as they -- as they require, I just -- I'll just review.
Q. Okay. Have you ever rendered an opinion in litigation that was adverse to Johnson & Johnson or Ethicon, Inc.?
A. No.
Q. Did you take any notes while you were doing your preparation for your opinions?
A. I -- I'm a better highlighter than note taker.

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Q. Okay. I can never read my own notes, so I don't -- I don't even take notes.
Okay. So you don't have any handwritten notes regarding your opinions; is that right?
A. No, not on this.
Q. You mentioned the Reliance List. Was the Reliance List originally prepared and provided to you by Ethicon counsel?
A. It -- it was given by counsel, but I can tell you that most of that Reliance List is trials that are relevant enough that I have read it over time.
Q. Okay. So then as you performed your own research and found additional articles, you would then submit them to Ethicon's counsel and then they would get added to the Reliance List; is that right?
A. Right. That's -- whatever I want to add up, I just submit.
Q. And that Reliance List is exhaustive other than a few of the articles that we've identified today, is that right, that have been marked?
A. Right, that's -- this is what includes it.
Q. Does your Reliance --
MR. SNELL: Could I make -- let me just make

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a note on the record. He did bring another thumb drive with a lot of Ethicon documents and materials that he had in his possession and, obviously, those would go and make up part and parcel of his knowledge base as well.

MR. DE LA CERDA: I'm glad you brought that up because I forgot to mark this thumb drive.

THE WITNESS: Can you just take a look because I want to make sure I brought the right thumb drive.

MR. SNELL: Okay.

THE WITNESS: I just dump it and I really never review it.

I'm seeing one of the slides have the name of a patient.

MR. SNELL: How do we deal with that? because it looks like an image.

THE WITNESS: It's an image, yeah, it has a name of a patient.

MR. SNELL: It has to be redacted.

THE WITNESS: Yeah.

MR. SNELL: Why don't we take it off the thumb drive and we can figure out how to redact it.

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So Peter, just for your reference, we're looking at the thumb drive Dr. Sepulveda brought. There is a PowerPoint titled "Pillowing, P-i-l-l-o-w-i-n-g, .ppxt, and it's got patient identification information, so we'll take that off the thumb drive and figure out how to redact that. It looks like it's images. I can't even read the name, but obviously once you open up the file in realtime you can see it.

MR. DE LA CERDA: Okay. So for purposes of the record, we're going to reserve --

Did we already reserve 17?

THE COURT REPORTER: Yes, for --

MR. SNELL: I think 17 was invoices.

MR. DE LA CERDA: Okay. So for purposes of the record, we're going to reserve Exhibit No. 18 for a thumb drive that Dr. Sepulveda has brought here today.

Q (By Mr. De La Cerda) And, for the record, Dr. Sepulveda, can you tell us, generally speaking, what is on the thumb drive that will be marked as Exhibit 18?

A. It -- it has the presentations that I have used for Prolift throughout the years, and it has the

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presentation on Gynemesh, and it has the surgical videos, and it has pictures of surgery that I have included in those presentations.

MR. SNELL: Did you mention this product?

THE WITNESS: TVT-Secur.

Q. (By Mr. De La Cerda) And, apparently, there are patient-identifying information on that thumb drive and so that information is going to be redacted and then the thumb drive will be provided at a later date; correct?

A. There is one slide that has the patient ID.

MR. SNELL: What I was going to do is take the file titled "Pillowing" with the patient-protected information off the thumb drive, put it on my local computer, and figure out some time today if this law firm can redact that.

MR. DE LA CERDA: That would be perfect.

MR. SNELL: But you'll have -- I mean, but we'll mark the thumb drive, because I want a copy of it, too.

MR. DE LA CERDA: Okay.

MR. SNELL: I'm just looking for -- is that your data?

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THE WITNESS: Yes, that's my own data.

MR. SNELL: Tell him about that.

A. I also included data of my own complications.

Q. (By Mr. De La Cerda) Let's discuss them. Actually, you know what, we'll come to that shortly.

MR. SNELL: Is that the same as the earlier stuff without the patient identifying --

THE WITNESS: No, that's -- I put all the files that have to do with it, so I had the files that I use to prepare the presentation, and I have the actual file slides with the presentation.

MR. SNELL: Did you mention this product?

THE WITNESS: That's TVT-Secur.

MR. SNELL: This one?

THE WITNESS: And there's another presentation on TVT-O.

MR. SNELL: Okay. Let me pull that one off.

Q. (By Mr. De La Cerda) Okay. And we'll come back to the data on your own complications, too. We'll discuss that in a moment.

Okay. Directing your attention back to Exhibit 16 -- oh, wait. Is this report -- in

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Exhibit 16 is your general report on TVT and TVT-O; correct?
A. That's correct.
Q. Is this report a complete statement of all general opinions that you'll express as to the TVT and the TVT-O and the reasons for those opinions?
A. That report includes that, up to -- up to today.
Q. So up to today, that report is a complete statement of all general opinions you'll express as to the TVT and TVT-O and the reasons for those opinions; correct?
MR. SNELL: Form.
Go ahead.
A. That's correct.
Q. (By Mr. De La Cerda) Does this report, your Reliance List, and the materials you've brought today include all facts or data considered by you as of today in forming your general opinions about the TVT and the TVT-O?
A. Yes.
MR. SNELL: I took the one file off so you can go ahead and mark that.
MR. DE LA CERDA: All right. So I am, for

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the record, marking the thumb drive that we've just discussed that Dr. Sepulveda brought as Exhibit 18.
(Plaintiff's Exhibit No. 18 was marked for identification.)
Q. (By Mr. De La Cerda) Okay. Now, Doctor, directing your attention to Exhibit 15 and that's your report on the Gynemesh, Prolift and Prosima; correct?
A. Yes.
Q. Now, is this report a complete statement of all general opinions you will express as to the Gynemesh, Prolift, and Prosima and the reasons for those opinions as of today?
A. Yes.
Q. And does this report, your Reliance List, and the materials you brought today include all facts or data considered by you in forming your general opinions about the TVT and the TVT-O as of today?
A. Yes.
Q. Okay. Let's talk a little bit about your practice. Where do you currently have privileges?
A. At South Miami Hospital, Baptist Hospital, and South Miami Medical Arts Surgery Center.

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Q. And do you currently perform surgeries to correct stress urinary incontinence?
A. Yes.
Q. Now let's focus over the last ten years.
Over the last ten years, what surgeries have you performed to correct stress urinary incontinence?
A. I have performed Burch procedures, TVT, retropubic, and transobturator inside-out.
Q. Is that TVT-O?
A. That's correct, that's TVT-O.
And TVT-Secur, TVT-ABBREVO.
Q. Okay. Any others that you can recall sitting here today?
A. I -- I recall doing 50 outside-in slings.
Q. Fifty outside-in slings.
A. Slings.
Q. Okay. Do you recall the brand of those?
A. That was from AMS.
Q. AMS. Is that the Monarc?
A. Monarc.
Q. You mentioned that you performed Burch as a surgery to correct stress urinary incontinence. What to you would be an indication to perform a Burch as opposed to a synthetic midurethral sling?

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A. I perform Burches rarely and I cannot -- I cannot really remember off my head my last Burch.
Q. Why do you perform them rarely?
A. Because midurethral synthetic slings work very well.
Q. Performing a synthetic midurethral sling, it's a quicker procedure than a Burch; right?
A. It's just more than -- than quicker. It performs -- short term and a long term, it performs better than a Burch and it's -- that has been -- has been my experience and that's what's supported by data.
Q. Okay. So -- but are there any indications to you -- when a patient comes into your office and you're going to perform a surgery to correct the stress urinary incontinence, what indications do you say, I'm going to perform a Burch instead of a synthetic midurethral sling?
A. My first option is a synthetic midurethral sling and I counsel the patients on it. There may -- I may have a patient that may say I want a Burch for one or other reason.
Q. Okay. So it's the patient making the decision that they prefer a Burch over a synthetic

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midurethral sling as opposed to you recommending the Burch as the first option?
A. My patients are -- I have a well-educated practice and they -- they actually may -- may bring great questions about one or the other. My experience is that they will follow my -- my recommendations.
Q. Right. Do you recall any instance where you've recommended a Burch over a synthetic midurethral sling?
A. There -- there was a time about when TVT came in and for one or two years that we spoke in those terms, but once randomized controlled trials came in, it was -- I tell them that that's basically -- is the best evidence that I have.
Q. Your understanding was that at least at one time the Burch was the gold standard for correcting stress urinary incontinence surgically; correct?
A. I -- I'm going to take exception to the "gold standard" term, but there was a time in which the Burch was the correct clinical -- clinical practice.
Q. Would you use the gold standard term to describe a synthetic midurethral sling?
A. I -- I just try to shy away from "gold

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standard." I think that clinically, it's -- the current clinical standard is probably a better -- a better term.
Q. So a current clinical standard is a better term to use than the term "gold standard"; right?
A. I -- I agree.
Q. Did you -- in the last ten years, have you ever used slings using biologic materials?
A. I -- I don't know if it's within the last ten years, but I -- I have used slings using autologous, I have done slings using dermis cadaver material. I may have used them one time posing, but this is so -- so remote that -- that I cannot tell you how many or which brand did I use.
Q. Do you remember any reasons why you would have used those biologic slings?
A. If I had some- -- if I had someone that -- that was -- the person that comes to mind is my -- the last pubovaginal sling and it was a smoker with -- with bad pressures in the urethra and I used the pubovaginal sling in that patient at that time.
Q. What do you mean by "bad pressures"?
A. Very, very low pressures in the urethra.
Q. Okay.

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A. It took very little for her to leak.
Q. Okay. And so why would it be that you would use a biologic sling under those circumstances?
A. I use actually her own fascia and it -- it was -- we didn't have anything -- anything -- we have things that were synthetic but that were not well-studied at that time.
Q. So this would have been, I assume, in either the late '90s or early 2000s?
A. That's a wide range, yes.
Q. Okay. You mentioned TVT Retropubic, TVT-O, TVT-S, and TVT-ABBREVO that you performed in the last ten years.
Do you know approximately how many of each of those you performed?
A. I -- I counted about -- at one time it was about 300 slings a year.
Q. Okay. And do you know what the breakdown was of those 300 per year as to the TVT Retropubic, TVT-O, TVT-S, and TVT-ABBREVO?
A. It was an evolution from TVT Retropubic to TVT-O and to TVT-Secur and then ABBREVO.
Q. Okay. So over -- over time, you might -- you know, you started with a TVT Retropubic, then

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you -- then you preferred the TVT-O, so you would switch to that; is that right?
A. Yes.
Q. And then you would prefer the TVT-S and you would switch to that?
A. Yes.
Q. And then later you preferred the TVT-ABBREVO and switched to that; is that right?
A. Right.
Q. Do you still perform TVT-Os, though, or do you just kind of stick with the TVT-ABBREVO?
A. I do it at the surgery center so we choose one. And since I do most of the slings, and I'm the medical director for the surgery center, I decide I'm going to use this or that one. We still have TVT-O on the shelf, but we -- we use TVT -- TVT-ABBREVO.
Q. Okay. Why would you prefer a TVT-ABBREVO over a TVT-O?
MR. SNELL: Form.
A. I have not found a scientific -- a scientific reason for it except for the fact that -- that it's the most recent product and it's -- it's a 12-centimeter sling instead of a longer sling.
Q. (By Mr. De La Cerda) What's the

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significance of it being a shorter sling as opposed to a longer sling?
A. It's -- I decided that if I can do it with 12 centimeters, I'm not going to use 19 centimeters when the evidence is good in my practice.
Q. Is -- you agree with the general theory that less foreign body is better when it comes to these types of procedures?
MR. SNELL: Form.
A. No, I think that there are physicians that have a level of comfort with TVT-O or, for that sake, with TVT Retropubic, and that being with a 5-millimeter needle, a 3-millimeter needle.
Each physician has his own level of comfort and they're going to use what works well for them. I have not found any scientific evidence that points out to one being better than the other based on that.
Q. (By Mr. De La Cerda) What about the general -- do you agree with the general proposition, though, that more foreign body will cause more foreign body reaction within the human body?
MR. SNELL: Objection, asked and answered.
A. It assumes -- it assumes that there's -- the

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term "foreign body" probably is the same -- in the same area as "gold standard." They're -- they're very wide, very unscientific. They -- in terms of the material that you leave in the area, if a physician would come and ask me, "Do you think I should do this because it leaves less material," I could not tell him with certainty, "Yes, you definitely need to move from one to the other." I have no evidence to support that.
Q. (By Mr. De La Cerda) And so, ultimately, you switched to the TVT-ABBREVO just because of your personal experience with it?
A. It's easier -- easier to keep on the shelf, the TVT-ABBREVO. If -- I guess, right now, if there would be -- there would be only TVT-O, I would be perfectly comfortable with it.
Q. Okay. Do you know whether TVT-ABBREVO comes in laser cut or mechanically cut?
A. Laser -- it comes in laser cut.
Q. TVT-ABBREVO is only laser cut; right?
A. Right.
Q. Do you know whether the Burch procedure is still taught in medical school?
A. I don't know.

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Q. Is the Burch procedure within the standard of care?
A. I think that for a physician that wants to do Burch procedures, that may apply.
Q. You wouldn't criticize another doctor for doing a Burch procedure over a synthetic midurethral sling; right?
A. I would not be -- be critical. I can share it, the evidence, but there's -- there's no reason for being critical over the Burch procedure.
Q. Are pubovaginal slings using native tissue still taught in medical school, to your knowledge?
A. No, I don't think they are taught -- I probably don't know, but I don't think they are.
Q. And if a physician performed a pubovaginal sling using native tissue, would you criticize him or her for doing that?
A. That's -- I have to say that's an excellent question because it's -- it probably is the procedure that would prompt me to say, "Listen, you need to reevaluate on how you're taking care of these patients," because that can be a morbid procedure.
Q. So that one is a little more borderline for you?

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A. Yes.
Q. Yeah.
A. And I can -- I can do that well -- I want to think that I can do it well because I did it well at one time, it's just that it's -- in terms of morbidity and seroma and wound complications and obstruction, it's -- it's a different -- different surgery.
Q. Would you consider it to be within the standard of care or no?
A. I -- I think that in certain areas, probably if that's -- we go to areas where they don't have what we have, that could be considered standard of care.
Q. You've never done a study to determine what percentage of medical schools are teaching Burch or pubovaginal slings using native tissue; right?
A. No, I don't know that.
Q. In your career, how many revision or excision surgeries involving synthetic midurethral slings have you performed?
A. I -- I think I have done three. I may have done more than that. Just in my mind it's -- it's infrequent enough that I actually -- one of the presentations on the thumb drive is me excising a sling, the pictures. That's how infrequent it is.

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Q. So to -- I'm sorry, I didn't want to cut you off.
A. So I actually consent to the patient and I said, "This is unusual." I consent to the patient to have it removed.
Q. Okay. So to your recollection, you've done three revision or excision surgeries involving synthetic midurethral slings?
A. I don't want to come into a fault -- faulty memory, but I can recall about three.
Q. Okay. Of those three, how many were you able to remove the entire sling?
MR. SNELL: Form.
A. On the -- it's probably two of them, the entire -- the entire sling being up -- up to the descending pubic ramus in that area. I remove the entirety of it.
Q. (By Mr. De La Cerda) And so that was -- that's the portion that is actually under the urethra but not the portion that goes into the pubic ramus; is that right?
A. The portion that gets about -- to about 1 centimeter from the obturator internus muscle.
Q. Okay.

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A. So anything that is beyond the obturator internus muscle, I -- I stay away from that.
Q. Is that because the risk outweighs the benefit of removing that mesh that's beyond the obturator internus muscle?
A. It's -- there are three factors to it.
Q. Okay.
A. The first one is that the orientation of the tape is very misleading to the surgeon. It comes forward to you and many surgeons, if they're inexperienced, they'll keep digging into the area and cause harm to the lateral side. That's one -- one of the other reasons.
The second reason is that I haven't found any -- anything convincing, and I keep looking for anything that has been written about excising that -- that portion of the -- of the tape.
And number three is that most of the time, 2, 3 percent of the time that we're going to revise a sling for avoiding this function, it makes no -- no -- there's no justification, I should say, there's no justification to go beyond that area.
Q. Okay.
A. Beyond the area within the obturator internus muscle.
Q. And of these three revisionary excisions -- let me first clarify.
Are the three revision or excision surgeries, are they all three excision surgeries or revision or both? How would you characterize them?
A. They are excisions. I was speaking about removing the whole thing.
Q. So those three were excision surgeries.
Were those three patients, patients you had implanted the sling or someone else?
A. I had one that I implanted the sling and two that came from -- came referred to me.
Q. Okay. So to your recollection, and you've implanted 300 synthetic midurethral slings for the last -- per year for approximately the last ten years; right?
A. Lately, they're -- the number of slings is less.
Q. Okay. So would a fair estimation be that somewhere between 2- and 3,000 synthetic midurethral slings is what you've implanted?
A. Yes.
Q. Okay. In the last ten years; right?

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A. Yeah, over the last ten years, yeah, that would be accurate.
Q. And of those 2- to 3,000 synthetic midurethral slings, your testimony is that you've only excised one of -- you've only, personally, excised one of the slings that you've put in; is that right?
A. Yes. That I remember, one. I may -- may have taken a segment or a fiber from another sling that I might have placed. I haven't kept track of it because the reality is that it's extremely rare. I'm going to tell you, what happens most of the time is you put the sling, the patient comes in, she's dry, she's happy, she moves on.
Q. What were the reasons why you performed the three excision surgeries that you can recall?
A. One of them was -- was just a tight sling on the patient. A young patient with a tight sling and she was having difficulty urinating.
I recall one -- another one was someone with a sling that was not a mid-urethra, it was higher. The sling was placed higher than the urethra and it wasn't working and I took that one and put one in the urethra.
Q. Any other reason that you can recall?

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A. No. I had -- I had one that came in because she had -- she had pain on the area of the insertion of the sling.
Q. Okay. So you had one with pain -- have you ever removed a synthetic midurethral sling because of an erosion?
A. Yes, I have. I have removed that erosion and I actually had one that I didn't put in -- put in those three. Now I recall one that she broke the incision and when I saw the patient coming on the third week, on the third week, I asked her, "How is it working?" She said, "Well, it's working."
And I examine her and she -- she had an exposure on the -- on the sling. She was honest -- honest enough to tell me, "Doctor, I was at home eating, I was choking on food and I threw myself over a chair and I felt -- I felt something." So she broke the incision line, and I saw it and I said, "Okay, well, I'll -- I recommend that you have this removed."
Q. So is that the -- is your testimony that's the only exposure -- or that circumstance you just mentioned, is that the only exposure where erosion of a synthetic midurethral slings that you had to treat?
A. No, I had a couple of exposures in the -- in

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the past, but it's something that either you give estrogen or you just take the fibers with a tenotomy scissors, which are using in reconstructive surgery, actually they're used in the eye and they have -- they're just perfect for this.
Q. I guess my crude understanding of that is it's like an in-office trimming of the exposed mesh; is that right?
A. It's -- you may have a few segments. In other words, you have not seen the whole incision open up.
Q. Okay.
A. And I -- I do remember a long time ago I saw a patient with a segment on one side. That's the only one I remember that the exposure was not in the midline on the incision. And that patient, I tried to convince her to let me take it and she said, "No, you're not going to take anything because it's not bothering me."
Q. So these are -- these are done -- this procedure you just mentioned, this trimming of the sling is done in-office, not under general anesthesia in surgery; right?
A. Right.

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Q. Have you ever performed an excision surgery or revision surgery because the patient was suffering from dyspareunia?
MR. SNELL: Form.
A. I -- I did one, same one that was having --
Q. (By Mr. De La Cerda) Pain?
A. -- the pain, yeah.
Q. Got it. Okay.
All right. The TVTs and the TVT-Os that you've placed, those have involved -- or have been mesh that is mechanically cut mesh and mesh that is laser cut mesh; right?
A. Both.
Q. Did that have anything to do with the time period in which you were implanting it or do you just -- did you stock both or what did that have to do -- any factors that that had to do with?
A. No, I did not have any specific reason to choose one over the other.
Q. Okay. Over the last ten years you performed surgeries to correct pelvic organ prolapse; right?
A. Yes.
Q. What types of surgeries have you performed?
A. I have performed anterior repairs, posterior

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repairs, enterocele repairs, iliococcygeal suspension, sacral spinous ligamentous suspension, abdominal sacrocolpopexies, robotic sacrocolpopexies, Prolift, graft reinforced repair with biologicals, augmented repairs with Gynemesh, perineoplasty.
I think I have mentioned probably all of them.
Q. The anterior and posterior repairs, did those include colporrhaphies?
A. Yes.
Q. Are those synonymous or --
A. Pretty much, yes.
Q. Okay. Now, all the repairs that you just mentioned, those are all within the standard of care; right?
A. Yes.
Q. Is implanting transvaginal mesh -- strike that.
Is implanting synthetic polypropylene mesh transvaginally still within the standard of care?
MR. SNELL: Form.
A. It's still within the standard of care if it will have the product available.
Q. (By Mr. De La Cerda) As of now, from the

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Ethicon products, Gynemesh is still available; right?
A. Gynemesh is still available.
Q. And do you -- is it your opinion that it's still within the standard of care to implant Gynemesh transvaginally for the treatment of pelvic organ prolapse?
A. I believe it changed, the actual indication or clearance. I may have read that.
Q. So the indication now is to use it for abdominal sacrocolpopexies; right?
A. Yes.
Q. So is it within the standard of care, though, to implant Gynemesh -- I'm talking about today -- so is it as of today within the standard of care to implant Gynemesh transvaginally for the treatment of pelvic organ prolapse?
A. Not -- not today.
Q. Okay.
A. Based on what I just stated.
Q. Okay. What was -- what was for you an indication in the past to implant synthetic mesh transvaginally for the treatment of pelvic organ prolapse as opposed to doing one of the other non-mesh

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procedures that you've mentioned?
A. I -- I came to the clinical appreciation that patients that have had a hysterectomy, patients that have had recurrent prolapse, patients that had a high degree of exertion, and patients that have a recurrent compartment or a contralateral compartment defect, those patients benefit from it.
I -- that's the general. I knew that I had patients that have -- I had one shot to take to the operating room and I -- for whatever reason, and those are the most difficult ones because they were more complicated, but on the other side, you wanted to give her the durability of the repair.
That's -- that's in general what I -- what I use when I counsel someone on the -- on the use of this synthetic graft. We started -- we started reading then, around the time that we had Gynemesh, more and more about durability and the repairs, specifically for those apical -- apical defects, so it became very attractive to treat patients on the apical, with apical defects, and when we didn't have to do an incision.
Q. Have you ever performed revision or excision surgeries involving synthetic polypropylene

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transvaginal mesh for pelvic organ prolapse?
A. Yes, I have.
Q. And how many have you done of that?
A. I look at those and they may be in the -- in the 10, 20, may be right -- right there based on what I saw the last time.
Q. So approximately 10 to 20 in your career revision or excision surgeries involving synthetic polypropylene transvaginal mesh?
A. That's -- that's a ballpark figure, yes. That's a very general figure.
Q. And of those 10 to 20, how many were you able to remove the entire mesh device?
MR. SNELL: Form, foundation.
A. In most of them -- most of them you can dissect the space -- the same space where you place it and you can -- you can remove it. It's -- if you have it in the muscle, obviously that's -- I already stated that there is no benefit of doing that. But if you dissect that area, you bring it up and you hydrodissect your segments, you're -- you can remove most of it.
Q. (By Mr. De La Cerda) Have you ever performed a revision or excision surgery because the

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patient was reporting pain and this is, again, I'm talking about patients with transvaginal mesh for pelvic organ prolapse?
A. You know, pain -- pain is rare after this kind of repair. What most frequently happen is that you would get in to have -- to remove an exposure, and then you end up -- you ended up removing more than what you thought you were going to remove because you had the plane and you were just dissecting the area and remove it. Then you ended up reinforcing the area with sutures.
There are times in which I -- I -- I say I have to do something to support it and it becomes such a subjective thing that I wish I could have explained this not now, but even when doctors would ask me the same questions and -- and be accurate and precise about it, but no, it's a general -- it's a general idea. What I'm explaining now is a general idea of what happens in the operating room when you're going to remove it. So you start small, but you start extending yourself on the dissection.
Q. So of the 10 to 20, though, how many of those did you remove for the reason of that they had -- they were experiencing pain?

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A. It's -- I think it's rare. I can't give you a specific number without -- okay, I want to be accurate and precise, but it was rare. The most recurring reason was an exposure.
Q. Okay. And did they report exposure with pain or no?
A. No. No. They -- most frequent complaint with the exposure was vaginal discharge.
Q. So were the 10 to 20 excision surgeries, were those primarily because of exposures?
A. It's -- it's -- mostly exposure and symptomatic exposures, exposures in which you saw granulation tissue.
Q. Of granulation tissue, okay.
Were any of the excision procedures performed specifically because of dyspareunia?
A. No, I don't remember anyone specific on dyspareunia. I remember taking one Prolift that was dyspareunia and pain.
Q. Have you ever -- have you ever had a patient come to you reporting dyspareunia or pain after having had a transvaginal mesh or pelvic organ prolapse where you believed it was the transvaginal mesh causing the pain or dyspareunia?

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A. No. Most of the patients that we see with dyspareunia, in a busy vaginal surgery practice, is without mesh.
Q. So you've never had that happen where you believed the dyspareunia was being caused by the transvaginal mesh; right?
A. By -- specifically by transvaginal mesh, no.
Q. Same question for the -- I don't know if I asked you for the slings, but have you ever had a patient come to you reporting pelvic pain or dyspareunia after having had a synthetic midurethral sling where you believed that it was the sling causing that pain or dyspareunia?
A. No, I -- I saw one sling that was low enough that I -- it could -- that could have been the source of dyspareunia.
Q. Okay. And I guess really you're thinking it's more the positioning of the sling as opposed to the actual sling; right?
A. Yes.
Q. Okay. How many Gynemesh PS's have you implanted in your practice, in your career?
A. Over a hundred.
Q. And how many Prolifts have you implanted in

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your career?
A. Definitely more than 100.
Q. Between 100 and 200?
A. Easily.
Q. How many Prosimas have you implanted in your career?
A. I did about 50.
Q. Okay. Turning -- we've now been going another hour. Would you like to take a break?
A. Yes, just quick as before.
(Thereupon, a recess was taken from 10:21 a.m. until 10:29 a.m., after which the following proceedings were held:)
Q. (By Mr. De La Cerda) Okay. We are back on the record.
Doctor, I wanted to direct your attention back to your CV, please, which is Exhibit 13. Just a couple quick things. If you'll turn to the fourth page, the section which is "Courses Presented."
A. Yes.
Q. The entities that I've seen -- well, the entities that are mentioned within this section where you've presented a course, the only entities I've seen mentioned are Johnson & Johnson, Ethicon Endo and

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Ethicon.
Are there any other entities mentioned here or no?
A. No, I never worked outside of Ethicon for any another company.
Q. Then under "Research Experience," which is, I guess, a couple pages later, is there -- do you have listed here any research on transvaginal polypropylene midurethral slings or transvaginal polypropylene pelvic organ prolapse mesh?
A. No, I did not do research on transvaginal sling. I rely on the randomized control trials.
Q. And then under "Presentations and Publications as Author or Coauthor," I didn't see any presentations or publications that involve transvaginal polypropylene midurethral slings or transvaginal polypropylene mesh for pelvic organ prolapse; is that right?
A. Yes, I did not -- I did not publish on transvaginal slings.
Q. We can set that aside for a second.
Okay. You're not a biomedical engineer; correct?
A. I -- I have a very good understanding of

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biomedical engineering.
Q. Okay. Would you consider yourself a biomedical engineer?
A. I do not get compensated for doing biomedical engineering.
Q. Okay.
A. And I did not graduate from -- with a degree of biomedical engineering. I do -- I do understand biomedical engineering well.
Q. I saw that you brought some books here that would relate to that, I believe. What is it that would provide the basis for your belief that you have expertise in biomedical engineering?
A. I have devoted years to understand it, to read about it beyond what any other physician that I ever met have done.
Q. Anything else?
A. I have studied, I have spoken to biomedical engineers, but specifically it's a passion and a dedication that I have had to understand it.
Q. Would you consider yourself an expert on the design of medical devices?
A. It goes right along with the biomedical engineering, with the surgical expertise that allows

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me to see what -- what can save in terms of efficiency in the operating room, what can I do better for my patients. That's what I use this for. This allows me to understand the design better.
Q. Have you ever, personally, designed a medical device?
A. I -- not -- not a medical device, but I have my own set of needles that I actually had made.
Q. What were those needles for?
A. For -- to approach the deep space in the pelvis.
Q. Were those used in connection with implanting mesh at all?
A. No, I use them for sutures.
Q. Okay. Have you ever been involved in the design of a medical device?
A. I -- I did give input to the design. It was not -- it was not my own patent.
Q. And what device was that?
A. Staplers for -- for -- staplers, a retractor, again, a circumferential needle.
Q. And these are all devices that are used in connection with surgery?
A. Yes.

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Q. Were you ever designed -- were you ever involved in the design of any transvaginal mesh devices?
A. Not in the devices of the ones that I use.
Q. Do you have any patents on medical devices?
A. No.
Q. Do you know what the standard is for a -- that a manufacturer must follow in designing mesh products?
A. I'm -- I became very familiarized with -- when I was with Ethicon by my own inquiries.
Q. What standards did Ethicon employ in the design of its mesh products?
A. It's -- it was from the initiation, from what they had an idea of what the device was, what the need was, and then there were -- I know there was a structure for research and development with the running of different -- different trials at different levels. And I get that information and submit it, along with other information that I was -- in which -- that had nothing to do with surgery, but cytotoxicity, paragenicity assays, cell cultures assays, and all this information submitted to the FDA, who would then review it and -- and within its own division for the

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device and then get back to them.
Q. Do you know what a manufacturer researches before a product is designed or released?
MR. SNELL: Form, overbroad.
A. The --
Q. (By Mr. De La Cerda) Let's take it a little more specific to the mesh products.
What did -- what, to your knowledge, did Ethicon research in regard to its mesh products before they were released?
A. I know that they -- they went through their suture -- suture research and -- and I know that they did experiments short term and long term with sutures.
I know that there was an opinion acquired from the field on the use of different sutures. Then there was a -- there was a use on the type of mesh that was used for prolapse on the different types of meshes. That wasn't done in the United States, that was done in France.
And there was also -- the materials were even evaluated in the same -- in the same way that sutures are evaluated, but also in the operating room. I'm aware of that one, too.
I'm aware that the needles and the approach

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that was used was evaluated by them before it was even used in the United States. And I know the packaging, the packaging was evaluated. I was able to see how they design the package for the operating room.

So all those lines never got to the place where they actually do the knitting of the material, never -- never got to see that, but I know there was a facility for that.

So there was a step of -- actually quite an elaborate chain that ended up giving the product.

Q. Do you know what types of experts were involved in the design of Ethicon's mesh products?

A. I spoke to materials engineers. I actually enjoy very much when I interacted with one of the biomechanical engineers over there that had a doctor's degree on biomaterials and I actually -- and I enjoyed that. I look at different -- they asked me for different types of materials. We look at -- they got my input on fibers.

I know that there was another group in France that was using those materials. One thing that I observed is that it would not just go with just one opinion, it was a consensus of different surgeons and different -- different settings.

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Q. Do you remember the names of any of the folks that you interacted with on those issues?

A. I can't -- I can't remember because it's over -- over five years and, you know, it's -- it wasn't a friendship that would continue beyond that. It was a work relationship.

Q. Do you know what a "design history file" is?

A. No.

Q. Are you familiar with industry standards that govern medical device design?

A. I read at one time, I read that. I read about ISO testing. I read about ISO testing. I read about the different toxicity assays and, actually, at one time I even may have read about the testing that was done for -- for meshes that was using sutures, i.e., I actually research it and read about it.

Q. Anything else that you can recall?

A. No.

Q. I'm sorry, is that --

A. I'm sorry. Not at this moment.

Q. Are you familiar with regulatory standards that govern medical devices?

A. I became -- I became aware of the regulatory standards. I knew about the classifications of

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devices. I had an idea of the classification of the devices and I had an idea, because I use other types of -- of devices that have nothing to do with mesh.

Q. What's your understanding of the classifications of devices?

A. I knew that heart -- heart monitors and nerve stimulators and intermittent nerve stimulator had a different classification than our meshes had and that surgical instruments would have and that sutures would have. You can -- you can just open -- you go to the operating room and get into one of the boxes of the sutures and you can pull that paper that gives all these different things about the sutures. So it's -- I knew I had -- I had an idea of the different -- at least three classifications that were used.

Q. Some requiring testing before they go out on the market, some perhaps not; right?

MR. SNELL: Form.

A. Some methods -- some methods did require different type -- different types of testing, different -- each one had different requirements.

Q. (By Mr. De La Cerda) Do you know how pelvic organ prolapse, transvaginal synthetic polypropylene mesh is currently classified?

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A. It's -- I read, recently, the classification for prolapse meshes and for -- they went up to Class 3.

Q. And what does that mean to your understanding?

A. They are classified as high-risk devices.

Q. Do you agree with that?

A. I -- I'll -- I agree with the approval that the FDA has and I'm not going to challenge the FDA or their panel on that one.

Q. Fair enough. Would you -- are you an expert in polymer chemistry?

A. I -- I don't design polymer chemicals. I do understand certain -- the polymers that are used in my specialty.

Q. And what polymers would those be?

A. When it comes down to polymers used in my specialty, it's polypropylene.

Q. Are you an expert in surgical pathology?

A. That -- that's an average over the last 25 years, I do look at slides.

Q. And that would -- that would be the basis for you stating that you had expertise in surgical pathology; is that right?

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A. I think that everyone that is a surgeon needs to have an expertise in surgical pathology.
Q. Okay. So that would be your basis for saying that; right?
A. That's correct.
Q. I didn't ask you this. What would be your basis for saying you have expertise in polymer chemistry, is it your experience?
A. My experience and what I read, the time that I devote, the time that I have devoted over the years to look at sutures and specifically polypropylene.
Q. Have you ever personally done chemical tests to determine if polypropylene mesh degrades?
A. I have not personally done -- done that testing. I did -- I did -- I have -- I read about it and have considered that hypothesis.
Q. Have you ever done a microscopic analysis of explanted polypropylene mesh to determine if the mesh degraded personally?
A. Not -- not with the purpose of degradation because I still -- I still looking for what -- what does degradation really mean in the pathology specimen.
Q. Okay. I'm going to shift gears a little

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bit.
Would it be fair to say that before a physician decides to utilize a transvaginal polypropylene mesh or sling to treat a patient, that it's necessary for the physician to warn the patient of all known side effects of the product, including severe ones?
MR. SNELL: Objection, form, speculation.
A. I think that before any -- any surgery, there has to be -- there has to be a full understanding of the -- as part of the informed consent. And when -- when that's happening, there -- there are factors that are going to play into it.
Yes, ideally, we should be able to clear our patients and get -- get a full understanding of it. There are times in which the patient cannot understand it and we have to find, as physicians and surgeons, a way to get them through the most relevance. But that including -- includes surgery with or without mesh.
Q. (By Mr. De La Cerda) Okay. So do you think that all the known side effects, including severe ones, should be disclosed to patients?
MR. SNELL: Same objection, form.
A. It's all known -- not only side effects, but

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essentially what -- what could happen that is within my control that is -- and what's not in my control and patients appreciate that we do that.
Q. (By Mr. De La Cerda) A physician should warn his patient -- his or her patient of characteristics of the transvaginal mesh or sling product that can significantly increase their risk of severe complications; correct?
MR. SNELL: Form, foundation.
A. On that counseling, the counseling should involve what has been tested. In other words, the last thing that you want as a patient is to be overwhelmed by just a wealth of data that is not clinically relevant, and we -- we have studies that actually address that.
Q. (By Mr. De La Cerda) So I think we might be getting to something there. If -- if a characteristic of a transvaginal mesh or sling product is clinically relevant, should that be disclosed to a patient during the informed consent process?
MR. SNELL: Same objection, foundation.
A. The informed consent addresses that.
Q. (By Mr. De La Cerda) So is that a "yes"?

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A. That would be in general a yes within -- within the parameters of that conversation between the physician and the -- and the patient. So it would be a yes with a condition that with knowing that that's very unique. That's a very unique interaction.
Q. Okay. Do you agree that a physician has a duty to inform his or her patients of the material risks associated with a transvaginal mesh or sling product before it's implanted in the patient?
MR. SNELL: Form, foundation, overbroad.
A. I -- I -- my opinion is that the patient should be informed not only of -- of the mesh, but if -- if surgery is being done with sutures, the patient should know that, too.
Q. (By Mr. De La Cerda) I mean, what I'm trying to do is use different terms for the risks or complications and in this one I'm using material risks associated with transvaginal mesh or sling product. Do you think that material risks should be disclosed to the patient?
MR. SNELL: Same objection, vague, immaterial.
A. Just to clarify, are you talking about the material or the material risk?

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Q. (By Mr. De La Cerda) That's a good question.

Material, that term I'm using -- because there's different ways that we've seen risks and complications associated with mesh products described by physicians. Sometimes they describe those risks as material risks, not as the material polypropylene, but as being relevant risks.

A. Oh.

Q. They're using that word.

A. I understand.

Q. That's a good question. Some doctors have used the term "material risk, "Yeah, I disclose it if it was a material risk."

Now with that explanation, do you believe that material risks associated with these products should be disclosed during the informed consent process?

MR. SNELL: Same objection.

A. The material risk associated with the whole extent of the procedure should be -- should be disclosed.

Q. (By Mr. De La Cerda) Okay. You mentioned the term "clinically relevant." Is that the same

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thing as clinically significant?

A. Um, clinically relevant is statistically significant.

Q. Could you explain what that means, what your understanding is of that?

A. It's -- with the best level of evidence that we have for what we're doing, explain to the patient this is -- we're going to translate it from the statistically significant to what's common and what's relevant in the surgery.

Q. Okay. I'm going to try and ask this properly.

Do you agree that a physician should warn his or her patients of risks or complications associated with the transvaginal mesh or sling products that are clinically relevant or statistically significant?

MR. SNELL: Form.

A. For the whole extent of the procedure.

Q. (By Mr. De La Cerda) Including the products, though; right?

A. Including the products.

Q. Okay. Now, the purpose of warning a patient during the informed consent process is to allow that

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patient to make a determination of whether she wants to undergo the surgery; right?

A. It's -- patients are going -- are going to eventually follow your -- the -- the doctor, the doctor's advice. But the reason why you do the informed consent is, more than the patient deciding, which many times they -- they cannot decide, it's to empower that patient with the information of this is what I use for my decision, the decision that I recommended to you.

Q. Okay. Ultimately, though, it is -- the patient has the right to decide one way or another what they want to do; right?

MR. SNELL: Form, overbroad.

A. Patient -- patients may -- may ask more questions or may -- say "I will have a preference," but in 25 years seeing patients, patients will tell -- will ask you, "Doctor, tell me what you -- you think is the best way of doing it and tell me why and how you come to that decision."

Q. (By Mr. De La Cerda) Okay. So have you ever had a patient say, after being consented or receiving informed consent, saying, "No, I don't want to have that procedure," as to mesh?

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A. No, I -- I have not had that experience.

Q. Do you agree it's important for the physician to have as much information about the risks associated with transvaginal mesh or sling product so that the physician can make an informed decision on whether to recommend those products?

A. I think it's important that the physician gets accurate and makes a reasonable effort to get better on what they use and what they do every single day.

Q. Including the information that they are going to communicate to the patient; right?

A. It's especially if you're going to communicate to the patient and -- especially when it has to do with you making a clinical decision.

Q. Do you agree that physicians rely on a transvaginal mesh manufacturer to provide them with information about the risks and complications associated with their transvaginal mesh products?

MR. SNELL: Objection, overbroad and requires speculation.

A. I can't -- I cannot think for all the physicians, but I -- I can tell you that their responsibility is within ourselves before we use any

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product.
Q. (By Mr. De La Cerda) Do you agree the transvaginal mesh manufacturers are at least one source of information that a physician can rely on in obtaining information about their risks and complications of transvaginal mesh products?
MR. SNELL: Objection, speculation.
A. It might be at the low end of the -- of the evidence that we gather.
Q. (By Mr. De La Cerda) You're not saying that a physician shouldn't rely on information from a transvaginal mesh manufacturer about the risks and complications of those products; right?
MR. SNELL: Form, overbroad.
A. I think that a physician needs to rely on the best evidence, best clinical evidence, not just in any sort of marketing communication or sales communication. They need to know that the decision to do surgery is a scientific process and they need to read that.
Q. (By Mr. De La Cerda) If -- but certainly if a transvaginal mesh manufacturer is providing a serious warning about its products, even if that warning hasn't played out in the scientific

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literature, I mean, that's still something that needs to be considered; right?
MR. SNELL: Form, overbroad.
A. There's a degree of information that you need to consider. You -- you have -- you're a doctor and you have the scientific information because that allows you to analyze information better. So in that regard, what we're going to see is information that is relevant because they're at the highest level of evidence, information that is less relevant because they are the lowest one, but there's a -- there's a hierarchy -- did I say that word okay? -- there is a hierarchy of information and we're going to go for the highest one.
Q. (By Mr. De La Cerda) Okay. Let's take a silly example for a second. If the manufacturer of transvaginal mesh knows that there's a one-in-a-million chance that it explodes inside a human body, but that is never played out in the RCTs, never, ever been seen by anyone other than the manufacturer, does that information need to be put out to the public and told to physicians?
MR. SNELL: Objection. I'm going to have to object, incomplete, purely speculative,

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hypothetical.
Q. (By Mr. De La Cerda) The answer is of course; right?
MR. SNELL: I don't know about that. I mean, that's the doctor's answer, but my objection is incomplete hypothetical, purely speculative.
Go ahead.
A. The explosion thing is a little out there. It's -- we have not seen any devices that actually explode for prolapse or incontinence. I don't know for the other ones.
The point I'm trying to come across is, to answer your question, when we look at information, we look at randomized control trials. Now, randomized control trials in cohort studies, even case control studies, you can go down to a list and you're going -- the methodology is what allows you to give recommendations and form your counseling.
Q. (By Mr. De La Cerda) So even if the manufacturer knows of severe life-altering complications associated with its products, if that severe life-altering complication hasn't played out in the randomized control trials, you believe that

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physicians shouldn't place much weight on that?
A. I think as humans -- as humans, if we see that there is any -- any danger for anyone, for any other human being, we'll just go and say it, regardless of who we work for. And at the end it's not a company, it's a group of people working. So the human -- the human nature is to -- the human thing is to actually do that, and that's our nature. But that's different from having -- making a clinical decision.
Q. Okay. So, ultimately, should information like that, if it's known to manufacturer, but it hasn't played out in the randomized control trials, should information like that about severe life-altering complications be communicated to a patient during the informed consent process?
MR. SNELL: Form, asked and answered.
A. What we're going to use to counsel patients is randomized control trials. And if -- if the question is if the manufacturer should disclose it, I -- I -- my opinion is probably most people would go ahead and disclose it, but in terms of making a clinical decision, we're going to use for the best evidence that we have.

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Q. (By Mr. De La Cerda) And I understand, I definitely understand. I guess what I'm trying to get at, though, is: Should that information be communicated to the patient during the informed consent process or not?
A. Only the information that is backed by good science.
Q. Okay. So the answer is; no, right?
MR. SNELL: Objection, asked and answered.
A. If it's not -- if it's not backed by science, it plays no role in the counseling of a patient.
Q. (By Mr. De La Cerda) Including if the manufacturer has discovered severe life-altering complications that it knows of, even though it hasn't been played out in the randomized control trials and the medical literature; right?
A. Our counseling --
MR. SNELL: Same objection.
A. Our clinical counseling is evidence-based.
Q. (By Mr. De La Cerda) Okay. And evidence from the manufacturer wouldn't necessarily count -- well, the finding of a manufacturer as to a severe life-altering complication wouldn't count as

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evidence under the framework that you're using; right?
A. The -- the findings, whatever findings, that being from a physician, that being from a patient, that being from -- from a manufacturer or anybody else, a group -- whatever findings needs to be corroborated by evidence, that's why we have studies, that's why we have a well-placed methodology for evidence.
Q. And so the medical -- well, the studies are going to be the foundation of that evidence, not some information from the manufacturer; right?
A. Any -- any -- any radical information, that being of things being too good or too bad need to be evaluated on the light of a randomized control trial, needs to be evaluated on if there is no randomized control trial, needs to be evaluated based on the type of the study that we have and the clinical experience.
Q. Do you consider a permanent injury a severe side effect?
A. A permanent injury is different from a side effect.
Q. Okay. So what -- so you don't believe that a permanent injury is a severe side effect or they're

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just totally different?
A. They're -- there's side effects and there's injuries.
Q. Okay.
A. And the side effect has more to do with what pertains to one particular product and an injury could be from anything that is used in surgery.
Q. Do you consider a permanent injury a severe injury?
MR. SNELL: Form, incomplete hypothetical.
A. I apologize for that.
Can you please repeat that?
(The requested portion of the record was read back by the reporter.)
A. There could be permanent effects of surgery that are not necessarily severe and severe that are not exactly permanent.
Q. (By Mr. De La Cerda) Do you consider a risk or complication that requires additional surgeries a severe side effect?
A. Based on the -- on the -- on the evidence on which -- which has a classification is not considered severe, is not considered severe if he needs just to go back to the operating room.

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Q. So that's not severe in your eyes.
A. Yeah.
Q. Do you consider risk or complication that seriously alters a patient's quality of life a severe side effect?
A. It could be -- that side effect could be for improvement of a quality of life, that could be -- that's an effect on the side or a side effect, the way we usually recognize it, can be deteriorating to the quality of life. I will have to look at the specific situation and look at the specific data on it.
Q. Okay. Let's shift gears. The content and substance of the professional education sponsored by Ethicon on it's TVT, TVT-O, Gynemesh, Prolift and Prosima did not and does not contradict the content and substance of the IFUs for these products; correct?
MR. SNELL: Form, overbroad.
A. The content of the -- of these programs use the IFU.
Q. (By Mr. De La Cerda) They don't contradict it; right?
A. No, there is -- there is actually -- in the presentations that you're going to see, they -- they work -- they work together.

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Q. Okay. Now, I figured the most efficient way to do this, because now we'll get into the substance of the various issues that you've opined on, there are many of these issues that can be grouped together as to all the products and I think that will be the fastest way to get through it, so that's what I'm going to do.

So, for example, I'm about to ask you about the IFU. I'm going to ask you about -- these are general questions about the IFUs of the TVT, TVT-O, Gynemesh, Prolift and Prosima. I think we can do it all at once.

A. Yes.

Q. First of all, are you familiar with the contents of the various versions of the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima?

A. I'm aware that they're -- they have changed in 2015.

Q. And you're generally aware of the contents, right, of those -- of those various IFUs?

A. Yes, there are IFUs that actually might be able to tell you separate steps.

Q. Okay. Do you intend to offer an opinion as to whether the warnings in the IFUs for the TVT,

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TVT-O, Gynemesh, Prolift and Prosima were sufficient to apprize doctors of the risks of those products?

A. Yes, I will -- I will give an opinion on that.

Q. And your opinion will be that they were sufficient warnings; right?

A. Yes, that will be my opinion.

Q. Do you know what standards Ethicon applied in terms of what needed to be included in the warnings in the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima?

A. That's the standards apply?

Q. Yes.

A. I'm aware of certain standards that were used for the IFU.

Q. Okay. And what were those?

A. The area on side effects, on warnings, procedure steps, and the specifics on informing about the need for specialized training to perform these procedures.

Q. Do you know what -- do you know whether there's any -- are there specific, like, written standards, though, that you're aware of that Ethicon used in deciding exactly what warnings would go in

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there, what adverse reactions would go in there, and what procedure steps would go in there? Do you know if there's any written standards that Ethicon relied on?

A. I'm -- I'm aware of that. As for many products, they -- the ones that are disclosed are the ones that are specific to that product.

Q. Okay.

A. In other words, they're not comprehensive guides on incontinence or -- or prolapse care.

Q. Okay. Have you ever, in your career, been involved in writing or preparing an IFU for a medical device?

A. I have not written an IFU. I read -- I read IFUs through most of my career.

Q. Have you ever studied the question of what risks and complications were known to doctors across the country with various background and levels of experience with regard to the use of the TVT, TVT-O, Gynemesh, Prolift and Prosima? Did you ever study that question?

A. The risk with mesh were, with these procedures in general, were addressed in a variety of ways. And those were -- there were communications

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from the American College of OB/GYN, there were meetings that -- there were journals, there were so many different -- different venues that we have grown used to read and understand.

The IFU, we -- we all expected that it was going to give us one specific set, but the other set on the evidence, we expected that from our -- our scientific data.

Q. So back to the question, though: Did you ever study -- ever perform a study or ever study or do questionnaires that determine what doctors actually knew about these products, about the risks and complications of those products? Did you ever perform a study like that?

A. There was -- to my -- to my knowledge, there's no -- not a study that have address -- address it.

Q. And you, personally, haven't done a study either; right?

A. No, I have not done -- done a study. I have examined forms on evaluation of surgical skills that at one time I use.

Q. Okay. But on this specific question, you haven't actually performed a specific study looking at

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what doctors actually knew about the risks and complications associated with transvaginal mesh products?
A. I have not performed such study.
Q. Do you agree that a surgeon should be able to solely rely on the warnings and description of risk and complications in the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima?
MR. SNELL: Form, incomplete.
A. We -- we don't rely just on the IFU.
Q. (By Mr. De La Cerda) Do you agree that a surgeon should be able to just rely on the IFU or do you disagree?
MR. SNELL: Same objection, asked and answered.
A. I -- I disagree that a surgeon should be -- rely just on the IFU.
Q. (By Mr. De La Cerda) Should the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima include the frequency, duration and severity of risks associated with those devices?
MR. SNELL: Same objection, lacks foundation.
A. No. As complete as an IFU could be, as

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complete as an IFU may want to be, it would not be able to address all of them. It may comply with what we expect from the IFU, but it will not be able to address every single -- every single risk that has to do with a surgery that is much more complicated than what an IFU can address.
Q. (By Mr. De La Cerda) The IFUs for the TVT TVT-O, Gynemesh, Prolift and Prosima should include all known material risks associated with these products; right?
MR. SNELL: Form, asked and answered.
A. It should -- it should include all -- all unknown risks about the material, but not necessarily will address all known material risk.
Q. (By Mr. De La Cerda) The IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima should include all characteristics of these products that can significantly increase the risk of severe complications; right?
MR. SNELL: Object to form, lacks foundation. This was asked and answered earlier.
A. Is the -- the instructions for use for the device, it addresses one area. The -- the rest is based on the data.

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Q. (By Mr. De La Cerda) So is that a no?
A. No, that's not necessarily a no. Actually, that's -- that's exactly -- the IFU cannot -- cannot be a comprehensive guide.
Q. So what -- what characteristics of these products -- strike that.
Do you believe that the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima sufficiently address any characteristics of those products that could significantly increase their risk of severe complication?
MR. SNELL: Objection.
A. As it pertains to the product, yes.
Q. (By Mr. De La Cerda) The information in the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima should be truthful; correct?
A. Yes.
Q. The information in the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima should be accurate; correct?
A. Yes.
Q. The information in the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima should be complete; correct?

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MR. SNELL: Objection, form. Prior testimony.
A. It is complete -- it is complete for the product. That's my -- my opinion.
Q. (By Mr. De La Cerda) The information in the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima should be fair and balanced about the risks and benefits of these products?
MR. SNELL: Same objection.
A. It -- it should be fair and balanced for what pertains to the product.
Q. (By Mr. De La Cerda) Once an IFU is out there and -- for physicians to review, if Ethicon learned of a risk or complication that was not previously warned about in the IFU and it was a significant risk or complication in terms of the harm it caused to women, do you know whether or not Ethicon had an obligation to get that information in the IFU?
MR. SNELL: Objection, hypothetical, legal standard.
A. As long as it's evidence-based, yes.
Q. (By Mr. De La Cerda) Have you compared the differences between the IFUs for the TVT, TVT-O,

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Gynemesh, Prolift and Prosima, are you aware of the differences between them?
A. I have -- I have read those -- read those -- and I have read them many times and I have use it to explain the procedure.
Q. And so you've seen that over time there's been some updates to the IFUs; right?
A. Yes, I have seen that.
Q. Is there a single long-term randomized control trial for TVT, TVT-O, Gynemesh, Prolift or Prosima with safety as a primary end point?
A. I -- I -- they don't -- they're not all included. There is a randomized control trial that explains about safety of Gynemesh, there is a randomized control trial that explains for Prolift.
For each one of them, there's -- safety have been included. Not only have those randomized control trials explain about safety, they have -- it has spoken specifically about the percentage and the clinical significance of each one of the complications.
Q. Are any of the studies that you're referencing there, has the primary end point, though, been safety in the study?

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A. The safety -- the safety was evaluated on -- on Gynemesh.
Q. Do you know what the name of that study was?
A. Yes, yes.
Q. There is another one over here too.
A. Gynemesh. Gynemesh on the -- okay. So -- so on the -- to begin with the mesh, we have the Flood, F-l-o-o-d, paper on the use of Marlex.
Q. And what does that study show?
A. That's for the anterior colporrhaphy reinforced with Marlex mesh for treatment of cystocele.
Q. Is this one of the studies that shows it has a primary end point of safety?
A. It's not titled "safety," but they -- they conclude on that study that this is safe to use. And then there's Nicita, Giulia.
Q. How do you spell that?
A. Giulia Nicita, N-i-c-i-t-a.
Q. And what is that study?
A. And it shows exactly applications in terms of they were able to save -- to do it with safety.
So to be accurate to the response to your question, there's no study that says safety of

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Gynemesh on -- or safety of Marlex in the use -- use on -- for cystocele repair.
There's -- there are multiple studies -- I can go on with the list -- that cites safety as one of the -- of the things that they study.
Q. So the point of this -- by the way, this is not my question. I never -- this question, to me, never really gets me anywhere.
But the point is that all the studies that have been done on any of these mesh products, the number one end point is, is it effective; right? Is it effective and then, by the way, was it safe, too?
None of these studies is like number one thing safety; right?
MR. SNELL: Objection, overbroad.
A. The -- there's even a better level of evidence that speaks about safety and is when you compare the use of any of these products with what has -- with the -- with the safety profile when you don't use the product. And that's where the randomized control trial comes into -- into play.
The randomized control trials has the capability of evaluating something that I have use without mesh and compare it with something with mesh.

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And that has been used -- that has been reported for Gynemesh, it has been reported for Prolift, it has been -- was reported for -- for TVT and TVT-O, and it was so -- so consistently demonstrated that when it came to Prosima, it became a cohort study.
Q. (By Mr. De La Cerda) Is it -- is it your opinion that the studies show that any time that mesh products have been compared to whatever the alternative was, a non-mesh alternative, that the mesh products have been shown to be safer than the non-mesh alternative?
A. It's -- it has been shown not to have statistically significantly increased in the number of complications or the frequency of these complications.
Q. Right. But that's a good point. So it's been shown to be as safe; right? And really, the differentiating factor is whether it's more effective; is that fair?
A. It has been shown to be as safe and in some situations, it has been shown -- it has shown to be even safer.
Take, for example, the use in the initial study of Marcus Carey on mesh, on Prosima, and straight -- and the known use of an implant.

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When you compare, you see that the three patients that he had to operate for vaginal stenosis were the ones that did not have a mesh. So there you have an instance in which there was more complications with -- by not using mesh than by using the mesh.

Is that directly related to the mesh? And that's something that could be addressed with a randomized control trial.

When we do sutures, suture repairs, and we call them "native tissue repairs," in a randomized control trial or even when we do a cohort of sutures, we see complications on sutures in 36% of uterosacral ligament suspension, we see suture complications in sacrospinous ligament fixations, and when they're compared with mesh, there is -- there is much less.

Q. So on the issue of whether -- you know, the FDA came out with an opinion about -- they actually described that repairs with pelvic organ prolapse mesh are no more effective and might be more dangerous than the alternative non-mesh repairs; right?

MR. SNELL: Objection to foundation.

A. That -- that was the -- that was an opinion that they came in, in the small panel, analyzing the data, I don't know, for two, three days, but that's

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not -- I don't know for how many days they analyze it. I don't even know what papers they consider.

But the preponderance of the evidence in the randomized control trial is that it's not more dangerous.

Q. (By Mr. De La Cerda) Okay. So on that particular -- I'm sorry.

A. I apologize. I'll just turn it off.

Q. So on that particular issue, you disagree with the FDA; right?

MR. SNELL: Form, foundation.

I think that's misleading because there's two different time periods, Counsel.

A. I -- I disagree -- I disagree with -- with the FDA opinion based on everything else that I review and that I present on my report.

Q. (By Mr. De La Cerda) All right. Let's shift gears a little bit and talk some about this is a TVT and TVT-O issue.

You're aware that the TVT and the TVT-O can either be mechanically cut into its sling shape or laser cut into its sling shape; right?

A. It can -- the edges can be mechanically cut or laser cut or personically cut.

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Q. You're aware that Ethicon had evidence as early as 2006 that after elongation, mechanically cut mesh has a greater tendency than laser cut mesh to degrade, lose particles, lose structure, rope, fray and curl; right?

MR. SNELL: Form. Form, foundation.

Go ahead.

A. What -- what I saw in a picture was an uniaxial test done in a sling beyond the capabilities of a sling and beyond any forces that could be placed on a sling when used properly.

Q. (By Mr. De La Cerda) But you also saw in those pictures that at least under those circumstances, the mechanically cut mesh as compared to the laser cut mesh had a tendency to lose particles, lose structure, rope, fray and curl; correct?

A. They -- they show particles that we -- we have seen over -- over time, not only on that, but also in sutures. They -- in a picture, I saw a picture of it, and I saw the pictures of uniaxial testing and I saw the communications about it, but that's as much as I can say, I saw it.

Q. And you know that that information was in

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the files of Ethicon at least as of 2006; right?

A. I -- I don't know the time when the information was.

Q. Have you personally seen a TVT or TVT-O that has lost particles, lost structure, roped, frayed or curled in your practice?

A. The only time that I have seen it stretch like that is when I'm actually -- one that I was removing that I put a lot of force into it. That's -- that's a way much force that any patient could ever generate with a sneeze or cough.

Q. You mentioned the one patient that you had that you're removing the sling where it's too tight?

A. Right.

Q. Is this the person you were talking about?

A. That might be the same person; I cannot tell you with certainty.

Q. So when the mesh was placed too tightly, you saw -- would you call that roping or what was it that you actually saw?

A. I -- I -- I started dissecting it and I saw that she still had some -- and the only way I can -- I can recall it is because I actually saw those pictures yesterday in one of the -- of the slide sets.

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And all I could -- all I could see was that I actually had to -- had to pull on it from inside, normal attachment. This was not roped, this was not curled, this not -- there's no such thing that I could describe in telling in general terms or in scientific terms. I -- this was one -- one anecdotal case in which I -- that's the only one that looks like the dimensions stretch -- stretch on that device.

Q. So would your testimony be that you've never seen a TVT or TVT-O mechanically cut, lose particles, lose structure, rope, fray or curl in your own practice?

A. No, because it has a plastic sheath.

Q. So you've never seen that yourself?

A. No.

Q. Should the mechanically cuts -- strike that. Excuse me.

Should mechanically cut meshes tendency to -- in comparison to laser cut mesh -- so should that tendency to degrade, lose particles, lose structure, rope, fray or curl be included in the IFU for the TVT and TVT-O or no?

MR. SNELL: Objection, foundation.

A. I don't find a need to include that because

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that's something that has not been demonstrated consistently.

Q. (By Mr. De La Cerda) Is that -- is that your basis for that opinion or are there additional -- is there additional information that provides a basis for that opinion?

A. I have not seen any scientific evidence that the mesh curls or ropes or -- or -- or frays. Nothing that I can -- I can tell you that, okay, this is -- we -- we saw this observation on this patient and we have reported it consistently or out of this number of procedures that we did, this number actually showed that. And if it happened, what is -- how does that translate into the clinical -- and I keep talking with my hands because -- that will never get into the deposition, but the -- on the -- I have not seen that be reported or how that can translate into clinical -- into clinical behavior.

Q. So on this issue, the basis for your opinion is really the absence of information supporting this information should be in the IFU; right?

A. And the fact that there are multiple randomized control trials well -- well-designed control trials, surgical trials by good surgeons

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within groups that are well-respected within my specialty, that have not describe, not in a single time, not in any of these papers, that there is such a thing happening.

Q. If mechanically cut mesh's tendency in comparison to laser cut mesh to degrade, lose particles, lose structure, rope, fray and curl is clinically significant or clinically relevant, should it be included in the IFU for the TVT and TVT-O?

A. It --

MR. SNELL: Objection. Hold on, give me a minute.

Objection, improper hypothetical based on the particle.

A. It would have -- it would have to be reported. It would have to be reported by something -- by something dependent by randomized control trial.

If -- any attributes that being on any of the polar sides of things -- things working at one level or another in both sides of the spectrum needs to be validated by scientific testing.

Q. (By Mr. De La Cerda) This is a question that I'll have throughout several of these opinions.

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I want to make sure to say it in a way that you would agree with, because I want you to define for me what it would require for this information to suddenly be required to be in the IFU.

And so what -- what would be required from your perspective for the information about the differences between a mechanically cut and laser cut mesh on the issue of degradation, loss of particles, loss of structure, roping, fraying, curling, what would it take for that information to suddenly be information that needs to be in the IFU?

MR. SNELL: Objection, same objection as before.

A. To make it to the -- to the IFU, needs to be something that is independent of -- of just -- just the technique beyond what's described in the IFU. If you see something like a device or a suture breaking, it needs -- the IFU should say, do not make it so tight or place a spacer under the urethra in the case of slings. The IFU says that.

So -- so -- and the insertion of the needle or the removal of the plastic sheath is being done, there needs to be instructions in the IFU for the appropriate placement. So this -- this is not about

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saying this mesh curls or ropes or -- that's not -- that's not what the -- what I expect from IFU. What I expect is give me the proper technique so I don't put this material to this extremes that would cause it to behave this way.

Q. (By Mr. De La Cerda) So I understand the -- first it would need to be independent of the technique, but if the roping, fraying, curling, loss of structure, if it's clinically relevant and statistically significant, that would need to be in the IFU; right?

MR. SNELL: Objection, improper hypothetical, vague.

A. And to the -- and to the level that it would say, okay, this is -- this is how it happens in the clinical setting, not just in a machine.

Q. (By Mr. De La Cerda) And I guess that would be encompassed though -- I mean, if it's statistically significant through randomized control trials -- let me think about that. So it would need to be shown through randomized control trials that actually involve human implants, not just benched-up testing or whatever it is in the lab; right?

A. If you blind -- if you blind this study in a

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way that physicians don't know which type of mesh they're -- they're using, you could -- that would be a good start.

Q. Okay. Do you know if Ethicon ever performed a test like that, where they compared laser cut mesh versus mechanically cut mesh actually implanted in women?

A. I -- I don't see anyone placing any human through the stress that a machine could do -- could do that.

Q. But Ethicon never performed a study like that; right?

A. I'm going to give you a better -- that was a very unclear answer what I just gave you.

I don't see -- I don't see an implant being stressed to the forces that could be done in uniaxial testing. Uniaxial testing doesn't always translate into the behavior in the human body.

The IFU was good in addressing the area that was most important on the urethra and the design was good in addressing the placement and the -- and the confirmation of the mesh with the minimum of the formation.

Q. But back to the question. Ethicon never

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performed a study comparing mechanically cut mesh versus laser cut mesh in -- actually in women; right?

A. It's --

MR. SNELL: Foundation.

Go ahead.

A. It's -- I'm not aware of any study that was performed like that, in that model.

Q. (By Mr. De La Cerda) If mechanically cut mesh, TVT or TVT-O, loses particles when its implanted in a woman, is there potential for those lost particles to migrate into the woman's vaginal wall and cause pain?

A. That's a hypothesis. It has never been demonstrated.

Q. Do you know if it's possible or no?

A. It's medically -- it's medically -- medically possible, which is way below that within the -- within the settings of certain medical probability.

Q. Okay. Still on this mechanically cut versus laser cut issue. You agree that mesh -- that mesh and polypropylene slings that is too stiff or rigid can increase the risk of complications like erosion, voiding dysfunction, and urethral obstruction; right?

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MR. SNELL: Form.

A. No -- no study has been able to corroborate that.

Q. (By Mr. De La Cerda) So would you disagree with that statement?

A. I -- I would disagree to that statement based on the fact that there's no evidence confirming it.

Q. You know that in 2004, Ethicon tested laser cut mesh and found it to be more rigid or stiffer than mechanically cut mesh; right?

A. Regardless of the findings that Ethicon may have found, I'm not aware that they found one way or the other, and with all the research, it would not surprise me that they may have found one way or the other. The question is if that has any -- any translation to clinical symptoms and the ans- -- of the ones you described, and my answer to that is no evidence of it.

Q. Okay. So that leads to the next question and this is a question I'm going to have with all these opinions, but should laser cut mesh's greater stiffness or rigidity in comparison to mechanically cut mesh be included in the IFUs for the TVT and

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TVT-O?
MR. SNELL: Objection, lacks foundation.
A. No -- no -- there's no evidence that it could work one way or the other. Why would they include it in the IFU?
Q. (By Mr. De La Cerda) Okay. So let's talk about the bases for why it doesn't need to be included in the IFU. What is your basis for that?
A. It's a -- the use of a laser cut or mechanical cut meshes do not translate into your procedure being performed any differently and they -- with laser cut or without or with mechanical cut, what you need to be aware is not to place a sling under excessive tension, which is something that we have learned even before there was mesh, not to place a sling under excessive tension, follow good surgical principles. And if there was any question about that, then doctors could have -- could have requested to be trained on it, but I would not include something on the IFU that would just confuse the issue on how to -- how to perform the procedure.
Q. Okay. If laser cut mesh has greater stiffness or rigidity in comparison to mechanically cut mesh, is clinically relative and statistically

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significant, should it be included in the IFUs for the TVT and TVT-O?
MR. SNELL: Objection, lacks foundation, improper hypothetical.
A. There's -- there's no correlate it clinically. So my answer to that is no, I would not expect them to write in the IFU.
Q. (By Mr. De La Cerda) So this is a hypothetical. I'm saying assume that it's discovered to be clinically relevant and statistically significant, under those circumstances would it then be proper to put it in the IFU?
MR. SNELL: Same objection.
A. If it's clinically -- clinically relevant or statistically significant, then it may have been included on the IFU if it pertains to the performance of the procedure.
Q. (By Mr. De La Cerda) Now, you're aware that -- you know Ulmsten is the original -- one of the original inventors of the TVT; right?
A. Yes.
Q. You know a couple of the guys that studied TVT with him were Nilsson and Falconer, you remember those names being mentioned in the studies?

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A. Yes.
Q. And you're aware that Nilsson and Falconer opposed the use of laser cut mesh because it did not have the same stretch profile of mechanically cut mesh. Are you aware of that?
MR. SNELL: Form.
Go ahead.
A. I am not aware of their internal conversations about it.
Q. (By Mr. De La Cerda) And does that have any effect on your opinion one way or the other?
A. It doesn't. Whatever -- whatever interaction they had, I would consider just a healthy scientific exercise, but until there's data supporting its use and there's data showing that there is a difference in performance, there is no need to make a difference -- to make a different recommendation.
Q. What is the proper way to tension the TVT device?
A. It's -- it's to do it tension-free and tension-free means that there is preservation of the width of the sling up to 75 percent.
Q. I think I missed something. What did you mean -- can you explain that again?

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A. By the time that I finish doing my procedure, the width on my TVT needs to be at least 1.1 -- at least 75 percent of 1.1-centimeter, that's not just with TVT --
Q. Okay.
A. -- that's with any sling that I may place.
Q. Where is that information in the IFU?
A. That's not going to be in the IFU because that's an observation of Jaime Sepulveda.
Q. Do you believe that Ethicon is responsible to tell physicians how to properly tension the TVT?
A. There's -- there's -- there's information on the IFU about not overtensioning.
Q. There's information about that, but is there information, like an exact measurement on how to tension? For example, I liked your example of 75 percent of 1.1 centimeters.
Does Ethicon have a responsibility to communicate to physicians an exact way in tensioning the TVT?
MR. SNELL: Form.
A. I think that Ethicon make every possible effort through their -- through their education programs to -- to emphasize good practices in doing a

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sling. Ethicon is not re-inventing our technique to do a continence procedure.
Q. (By Mr. De La Cerda) When you taught on behalf of Ethicon regarding slings, did you discuss this issue of the 75 percent of 1.1 centimeters indicating proper tensioning?
A. That's a concept that we all have -- have -- we, as surgeons, we know we don't want to bring it tighter than that. But we learned that with the pubourethral slings.
Q. Okay. So are you saying no, you didn't personally discuss that issue or because everyone already knew it anyway?
A. Right. This is -- this is a common surgical knowledge, which Ethicon may or may not have known. I don't know if they -- if they knew it. This is just a personal observation.
Q. So you believe that Ethicon properly instructs physicians on how to tension the TVT; right?
A. They -- they cover that in the IFU.
Q. Do you agree that the strongest unmet need with the TVT is the ability to adjust tension both intraoperatively and post-operatively?
MR. SNELL: Form.

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A. Well, there's no -- no way to assess post-operatively. You're going to close and there's no -- no study that says how you're going to tension it. We try to make an inference with biomechanics.
Q. (By Mr. De La Cerda) But do you agree with that statement? That the strongest unmet need of the TVT's ability to adjust tension both intraoperatively or post-operatively, do you agree or disagree with that statement?
A. I --
MR. SNELL: Form.
Go ahead.
A. I would agree to an extent, but it's so -- so vague that I cannot tell you that I agree completely with it.
Q. (By Mr. De La Cerda) Do you agree that the mesh and TVT may be too wide?
MR. SNELL: Form.
A. I don't -- no, I think it has shown to be of the -- of the right -- of the right width to work clinically.
Q. (By Mr. De La Cerda) Do you agree that there is no calibration to let you know when you have the tension right?

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A. That's -- that's part of the art of surgery that I described before.
Q. So you do agree with that; right?
A. Repeat that.
Q. So do you agree with, quote, there is no calibration to let you know when you have the tension right, close quote?
A. No, we know -- we know when the tension is right. We have experience -- enough experience to know when the tension is right.
It's extremely subjective, but I can tell you if you, at the end of your surgery, you see that width that goes underneath, that width that has been shown study after study, that is effective, if you know that is not the width you have at the end of your surgery, you overtensioned it.
Q. But there's not like a general calibration for that; right? Or is there? I mean, is the general calibration the 75 percent of 1.1 centimeters, is that the general calibration for everybody or no?
MR. SNELL: Form.
A. It's a visual inspection.
Q. (By Mr. De La Cerda) So is that a yes?
MR. SNELL: Objection, asked and answered.

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A. Yeah, that's a general calibration that is been used -- I'm sorry, Burt.
MR. SNELL: I said, objection, asked and answered.
Go ahead and answer it.
Q. (By Mr. De La Cerda) Do you agree that there is no -- quote, there is no consensus on the amount of tension needed and many feel that the tension will vary based on patient presentation and patient anatomy? Do you agree with that?
MR. SNELL: Form.
A. It's -- I would have to agree that it changes from patient to patient and that's one of the biggest challenges not only in this proceeding, any surgery.
Q. (By Mr. De La Cerda) Are you going to offer the opinion that tensioning of the TVT sling is the same regardless of whether the sling is made of mechanically cut mesh or laser cut mesh?
A. You're going to visually see at the end of your procedure and you know if you tensioned it right when you look at it.
Q. So tensioning might change as long as the width that you're looking for is correct?

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A. I just say visually see. I don't know how another way you're going to see if it's not visually.
Q. Right.
A. But it's -- what I -- my opinion is that once you -- once you place a sling, that being laser cut or mechanically cut, at the end of your procedure, that sling needs to look the way -- in a way that it covers the mid urethra to an extent of at least .75 to 1-centimeter.
Q. Do you agree that a responsible medical device company would determine the proper way to place a device before putting that product on the market?
MR. SNELL: Form.
A. They -- they have no way -- we have no way to -- to -- to communicate that to each other. That is -- that is the hard part of surgery.
I think that when they say, "Do not overtension it," and when they say, "You need to have experience in continence procedures," and when they say, "This is not a comprehensive guide for continence care," I think that's accurate and fair and as a surgeon you understand that.
Q. (By Mr. De La Cerda) And so this question is really more of a general proposition, though.

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Would you agree that a responsible medical device company would determine the proper way to place a device before putting that product on the market?
MR. SNELL: Same objection, asked and answered.
A. That's where -- that's where all the studies with cadavers come in.
Q. (By Mr. De La Cerda) So the answer is yes; right?
A. Yes, the device company does that.
Q. Okay. Shifting gears to a new issue.
Before I do that, are you okay? Do you want to take a break at all?
A. No, I'm okay, if you guys are okay.
MR. SNELL: What time are we going to have lunch?
MR. DE LA CERDA: Yeah, it's almost noon. Do you want to do it now.
MR. SNELL: If he's fine, I'm fine.
(Thereupon, a recess was taken from 11:47 a.m. until 12:00 p.m., after which the following proceedings were held:)
Q. (By Mr. De La Cerda) So we're back on the record.

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There's a fault question on -- earlier we discussed your work as a consultant for Ethicon and we briefly discussed what you estimated to be what you had received from Ethicon in compensation for that.
In another case, the Raviola case, which you may recall, there was actually a production of the payments and it was produced in a -- in hard copy -- and this question is probably really for Burt.
MR. DE LA CERDA: If I forward that to you, can you send that to us in like an Excel or whatever it originally came in because the print is tiny?
MR. SNELL: Okay. Yeah, I mean -- well, I can do my best.
MR. DE LA CERDA: Okay.
MR. SNELL: I've been trying to send e-mails. My e-mail is not working. It's not letting me send stuff. I have something important to send. It's not related to this deposition. I've been trying all morning. Is the Internet --
MR. DE LA CERDA: It's coming off and on for me.
I'm forwarding this to you and then if we

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can get the native version. It looks like it was an Excel that was then printed off, but the type on it is really small and then that will provide -- this is what Ethicon shows its records of payments and then that can kind of settle that issue.
THE WITNESS: Yeah, it was actually presented on the Cavness trial.
MR. DE LA CERDA: Oh, okay.
THE WITNESS: It was in very small -- very small letters.
MR. DE LA CERDA: Okay.
THE WITNESS: And just as clarifying that number, what was allocated to pay me, not actual payments.
MR. DE LA CERDA: Okay. So we'll have to clear that up, but if, Burt, you can take a look at getting us that version, thanks.
Q. (By Mr. De La Cerda) Okay. All right. The issues that I'm about to discuss will relate to TVT, TVT-O, Gynemesh, Prolift and Prosima, so I'm going to do it all at once.
First, you're aware that the TVT and TVT-O are made of Prolene mesh, which is constructed of

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knitted filaments of extruded polypropylene strands, identical in composition to that used in Prolene polypropylene nonabsorbable surgical suture; correct?
A. I agree with that.
Q. You're also aware that the mesh in Gynemesh, Prolift, and Prosima is Prolene Soft, which is also constructed of knitted filaments of extruded polypropylene identical in composition to Prolene polypropylene suture; correct?
A. To a -- to a -- identical in composition, yes.
Q. And the IFUs for the TVT, the TVT-O, Gynemesh, Prolift and Prosima all characterize Prolene as inert; correct?
A. They -- they characterize it as that word inert, yeah.
Q. They state: "This material, when used as a suture, has reported to be nonreactive and retain its strength indefinitely in clinical use"; right?
A. I -- I'm aware of that statement, yes.
Q. They also -- the IFUs for those products also state: "The material is not absorbed nor is it subject to degradation or weakening by the action of tissues enzymes"; right?

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A. That's a statement on the IFU.
Q. The mesh in these products not being -- or strike that.
The mesh in these products being nonreactive or inert or not subject to degradation, that's a property or those are properties that are desirable for an implant designed for a human body; right?
MR. SNELL: Form, overbroad.
A. That -- that is -- that is a characteristic that we did not see in other types of materials and that we're pursuing when we placed those sutures.
Q. (By Mr. De La Cerda) Okay. Why would you want a human -- an implant designed to be implanted in humans to be inert or nonreactive or not subject to degradation?
MR. SNELL: Objection, overbroad.
Go ahead.
A. The degradation has to -- has to do with -- the way we interpret degradation has to do with absorbables or partially absorbable sutures.
The way that non- -- nonreactive means that there's no reaction to hydrolysis.
And the way that it was described as non- -- nondegraded is it was that there was no loss on the

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strength of the suture on testing that was done before placing it on a patient.
Q. (By Mr. De La Cerda) Okay. So why would it be desirable for a human implant to have those characteristics that it doesn't degrade, that it's inert, that's it's nonreactive?
MR. SNELL: Same objection.
Go ahead.
A. It is -- it translates, theoretically, on the durability of the repair.
Q. (By Mr. De La Cerda) Because these mesh implants are intended to be permanent implants; correct?
A. They're intended to -- to last a lifetime if you can make it interact in a way that it can last a lifetime. In other words, if the host doesn't change, you'll want that implant to work and give you durability.
Q. Now you're aware that as early at 1987, Ethicon had evidence of degradation of Prolene in the human body; correct?
A. I -- I don't believe that they call it degradation in the sense that we interpret degradation. There's -- there's degradation from the

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biomechanical point of view and there's degradation from what we see in normal life of degradation.
Q. Okay. So what is it that you believe that Ethicon saw in terms of degradation in 1987?
A. Well, what they saw -- what they saw is purely a microscopic study. If there will be degradation, there will be a significant impact on the durability of the effect of the sling or in the durability of the repair.
Q. In the context of safety, though -- strike that.
If Prolene has a tendency to degrade in a human body, would that indicate that it's not inert?
MR. SNELL: Form, improper hypothetical.
A. If it would degrade, it would dissolve. And if it would dissolve, it would just lose all its effect. So whatever -- whatever conclusion is met of degradation is on hypothetical grounds and not based on the evidence that we have.
Q. (By Mr. De La Cerda) What evidence are you referencing?
A. The durability of a procedure for incontinence on prolapse.
(Brief interruption and off the record discussion.)

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Q. I can't remember if you were finished with your response. If you could read it back.
(The requested portion of the record was read back by the reporter.)
A. Let me clarify this. The reason why I generalize it on incontinence on prolapse is because we're talking about more than one product here.
Q. (By Mr. De La Cerda) Yes, yes.
And all these products have, within their mesh -- one mesh is called regular Prolene or just Prolene and the other one is called Prolene Soft, but both meshes are made of essentially woven Prolene suture. It's the same material as Prolene; right?
MR. SNELL: Objection.
A. No, it's not woven.
Q. (By Mr. De La Cerda) How is it made then?
A. It's knitted.
Q. Knitted, okay.
But it's all made of knitted polypropylene that's identical in composition to Prolene; correct?
A. It's knitted -- it's knitted extruded polypropylene.
Q. It's identical in composition to Prolene suture; right?

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A. It is -- it has been shown to have the same level of crystallinity as Prolene suture.
Q. If there were findings as to Prolene suture, would those findings, the characteristics of Prolene suture, have relevance to meshes that are also made of extruded polypropylene that's identical in composition to Prolene suture?
MR. SNELL: Form, vague.
A. I did not get that one. Sorry.
(The requested portion of the record was read back by the reporter.)
A. As it pertains to composition, the evidence shows that TVT-O and Prolene sutures, that's the extent of the evidence, has -- has the same crystallinity. When we define crystallinity, is the most accurate way to evaluate that one material is like the other.
Q. (By Mr. De La Cerda) Well, what I'm saying, though, is if there is a finding about a characteristic of Prolene sutures like, for example, degradation, if Prolene sutures degrade in the human body, can we also say or is that evidence of that Prolene mesh would also degrade in the human body?
MR. SNELL: Form.

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A. And there is -- first of all, there is more -- there are three -- there are three parts to that question. The first one is the concept of degradation. And if Prolene would degrade, all the Burches that we did with polypropylene would eventually fail. And all the -- and most of the slings that we did with polypropylene would eventually fail clinically.
And we know that the evidence points out that that's -- that's not the case. That's the first part of degradation.
Number two is polypropylene, the way it defines degradation on a dog or in a rabbit or in a Himalayan or a Wistar rat or a Himalayan -- Himalayan rabbit, the way it's defined cannot be translated to -- to a -- to a person because they're completely different hosts and the stresses that are placed on -- on those implants are completely different.
The immunologic reaction is different and the cellular level is different, cellular findings are different. And, finally, is the concept that -- that Prolene and -- would -- would degrade and create anything beyond what the sling would create. No, they stay -- they're both exactly the same, the same. Not

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exactly, but they're both very similar implants.
So those are the three -- three aspects to your question, and I know it's an extremely elaborate answer for probably a much more straightforward question. But there's -- the concept of degradation, I would have to accept that concept to agree with your -- with what you just presented.
Q. (By Mr. De La Cerda) I think step one is we need to define what we're talking about by degradation.
We know that in 1987 there was a study done by Ethicon on explanted Prolene suture from humans; right?
A. On explanted and not -- I believe it's from the dog study.
Q. There is one of humans, too. Have you seen that one?
A. No, I haven't -- haven't. I'm not aware of that one.
Q. Okay. If there's a study from 1987 on -- and these are Prolene sutures explanted from humans, if those show the cracking and degrading that's indicative of degraded polypropylene, that's the kind of degradation that I'm talking about.

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A. Are you referring to the eye study?
Q. I'm sorry?
A. To the eye study. Are you referring to the polypropylene being removed from the eye?
Q. Vascular -- I believe they were implanted in the heart. Unfortunately, I didn't bring that study with me. I assumed you would already be aware of it.
My understanding is they were explanted from the hearts of the patients. They were Prolene sutures explanted from the heart of human patients.
Are you aware of that one?
A. No, I'm not aware. I know there is a study on blood vessels and I know that there is a study of -- on the eye and I know about the dog study.
Q. Okay.
MR. SNELL: For clarification purposes, you have -- maybe if you knew -- I can tell you -- I know what the name of it is. I mean, if that would ring a bell with him.
MR. DE LA CERDA: Professor --
MR. SNELL: Gudion, blood vessels.
THE COURT REPORTER: Can you spell that one?
MR. DE LA CERDA: I think it's G-u-d-o-i-n or something like that. That's the professor's

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last name.
Q. (By Mr. De La Cerda) Does that ring a bell?
A. It's -- I am -- I read that. I do recall reading it and I do recall that it was a very thin polypropylene suture that was hand tied, but there's -- I don't know how that translate to degradation.
Q. (By Mr. De La Cerda) Okay. So the finding in that study was at the surface, that there was cracking on the surface of the suture; right? And that when they tested the material from the cracking, that it was indicative of oxidative degradation to polypropylene; right?
MR. SNELL: I'm going to object on foundation.
Go ahead.
A. I cannot confirm that, no.
Q. (By Mr. De La Cerda) Okay. Well, what I'm trying to do is define the degradation I'm talking about. And I think this is even in the studies that discuss it, degradation, and there have been in the studies discussion of the surface of polypropylene has some sort of cracking that's going

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on and when they look at that cracking, it's believed to be polypropylene that's cracking and degrading.
Now you've seen studies that have discussed that issue; right?
A. I'm -- I'm aware of the paper by Clavé.
Q. Okay.
A. By one of the Clavés, by the way, not --
Q. Is there a brother, like an evil twin?
A. So I am aware of that paper and in that same paper they cite the UV -- ultraviolet degradation, but I am also aware that that paper was about normal samples.
I'm also aware that the number of low-density polypropylene study was less than -- I believe it was a quarter of the sample and -- I don't have to believe it, I actually have it here.
Q. You're welcome to pull out anything you'd like to review.
What I'm trying to get at -- I'm just trying to get us to agree at least on a definition of degradation that I'm going to ask you about. And what I'm trying to say is that's the version of degradation I'd like to ask you about.

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Now, I know you're already going to tell me that's not clinically significant. I know you're going to tell me it's not going to matter. I know that. What I'm trying to first get is let's get an agreement on that's the degradation I'm talking about and then we can go through the -- to kind of finish up the questions because you'll end up telling me that it doesn't need to be in the IFU.
So focusing, first, on the degradation, the version that I'm talking about is the cracking, the surface cracking that happens of the polypropylene that's at least been seen and reported on in some of the studies. Is that version of degradation, is that clinically significant or clinically relevant such that it needs to be in the IFU for the TVT, TVT-O, Gynemesh, Prolift and Prosima?
MR. SNELL: Objection, lacks foundation.
Go ahead.
A. The way it stands right now, with the studies that I have seen, specifically the ones on -- in general polypropylene -- the ones on the eye, I believe I saw that. The way it stands right now, that type of degradation has not been shown on the -- on actual samples of slings. It has been shown in

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abnormal samples, not in slings that work or come -- or have the clinical results that we have seen on reports and it have -- it have not been shown in any -- any studies having a clinical impact.

Q. (By Mr. De La Cerda) Okay. What do you mean by "abnormal slings"?

A. If there is a sling that has an exposure, and especially slings that are exposed to a surface, then that will be abnormal sample.

Q. Okay. Exposed to what kind of surface?

A. To the vagina or the bladder or the bowel.

Q. Okay. So is there something that's happening during that exposure that -- that your belief is causing this phenomenon of degradation?

MR. SNELL: Objection. Hold on. Misstates -- I don't think he testified, Counsel, that he believes in degradation. I think you're taking what he said -- I think you're misstating his answer.

Go ahead.

A. The -- what we see in abnormal slings is that a biofilm is created and this biofilm is -- has been seen in catheters, it has been seen in IUDs, it has been seen in other implants that are exposed to

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air.

Q. (By Mr. De La Cerda) Okay. So is that -- is that your explanation of what you believe is actually being seen when we see this cracking?

A. That -- that is -- that is actually what -- what I see, the only correlation that I can put together with the cracking.

There's no other explanation based on what I know and what I have researched that mechanical stress retrieval or a biofilm.

Q. Okay. We know -- well, you know that raw polypropylene without any antioxidants would degrade in the human body. Do you know that or no? Or do you believe that or no?

A. No, there's no evidence that there's degradation.

Q. Okay. Do strong oxidizers like peroxide, do those affect raw polypropylene or no?

A. The only report that I was able to find on it was in containers, which is different from this -- it's the same hydrocarbon, but different containers on a surface outside.

Q. Okay.

A. Actual containers that were used for

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storage. This is completely different from -- from what is used in slings in prolapse. So there's -- it's a hypothesis. That's probably upgrading it to a hypothesis.

Q. Ultimately you believe, though, that the cracking that's seen when the studies are discussing degradation is really a biofilm and not the polypropylene itself; right?

A. I -- I don't know if it's the biofilm or it's a matter of technique or if it's a stressor that was placed on the sample on retrieval. We -- we don't know that. And most -- most importantly, we know that probably any -- regardless of the reason why it happens, it doesn't translate in any physical outcome, in a clinical significant outcome.

Q. What about the erosions, though? So you mentioned that they were abnormal meshes that had eroded and were exposed to air, isn't the fact there is an erosion, isn't that some sort of clinical -- clinically significant event?

MR. SNELL: Form.

A. No, the exposed segment of the sling doesn't mean that it eroded. The most frequently -- the most -- normally, the most frequent reason why you see

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an exposed sling or a mesh is because there's a bone healing that -- the dehiscence of the wound, there is a dehiscence of the wound, there is a disorder of the wound healing.

So we have seen disorders of wound healing in patients that have prolapse even before we place -- we replace it, and we actually have seen it with sutures. Not only with polypropylene sutures, we have seen it with polyester sutures, specifically, and we have seen it with GORE-TEX sutures.

And there's actual clinical evidence that shows these abnormal wound healing occurring on the presence of these sutures, and also with native tissue. So this is not that the sling work itself around and erode. This is an incision that has been open.

Q. (By Mr. De La Cerda) And is there any -- and what's responsible for the poor wound healing or the wound healing issue?

A. There are a variety of factors. These are defects in the fibromuscular layer, specifically, as I place -- as I wrote in my report, loss of tensile strength in the abdominal sutures that put the wound together.

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Number two, there are mechanical factors.
Number three, there are actual wound-healing factors, such as immune disorders, poor tissue healing, cigarette smoking, and finally hematomas, just to mention a few.
And these conditions may predispose a wound to open and expose the graft. It may predispose the wound not to heal properly over a suture and it may predispose the wound not to heal properly just over native tissue.
Q. Have you -- are you aware of an exposure and erosion ever happening not related to a wound healing issue?
A. No, that's -- that's -- is a problem of wound healing.
Q. And that's it?
A. And that's what I see consistently.
Q. But it's your belief that that's the only reason why there might be an exposure or erosion is because of wound healing; right?
A. It is the most viable factor of the three fact- -- of the three -- of the interaction between a graft on a host, is the most viable factor is the host. And the -- the sling's consistent. Or the --

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or the polypropylene is a consistent material. And there's obviously the third one, which is the insertion, the technique, but if you really look at technique being constant, it's always a wound healing issue.
Q. So one of the problems could be the doctor's fault, the other problem could be the patient's fault because of their body and their wound healing, but third issue can't be the implant because it is what it is and it's --
A. I would not simplify just with it being a fault. We -- this is not -- these are not issues that are just -- that just happened with -- with mesh. We -- we know that these issues go way -- for any prosthetic material, way back before any prosthetic material. We know that these issues happen with polyester sutures in uterosacral ligament suspensions. We know that there are instances in which there has been no mesh, there being a suture and the suture had to be removed. And we know there are instances in which we don't use a mesh at all and that incision opens up. The most viable aspect is the host. There's definitely a variation on the insertion technique and I think that by now we all have evidence

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that those with the most experience have the lowest rate of -- lowest rate of problems. Not only this surgery, any other surgery, but the most consistent part is the prosthesis, the polypropylene.
Q. Do you believe that mesh degrading or breaking down can lead to an erosion or exposure or no?
MR. SNELL: Foundation.
A. There's -- there's no evidence that that's the case.
Q. (By Mr. De La Cerda) Do you believe that polypropylene can become brittle?
A. How -- how do we define brittle?
Q. That's a good question.
A. You're going to probably --
Q. What's your understanding of the term "brittle"?
A. Brittle is weak. Brittle could be friable. Decreased tensile strength to put it in exact terms.
Q. So using that explanation of what brittle means to you, do you believe that polypropylene can become brittle?
A. No.
Q. Okay. So now let's get to the question

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about your opinion. Should Prolene's tendency to degrade in the human body be included in the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima?
MR. SNELL: Lacks foundation, misstates, opinion testimony.
A. There's -- there's nothing to place the result of degradation.
Q. (By Mr. De La Cerda) And your basis for that opinion is what?
MR. SNELL: Asked and answered.
A. That degradation has not been defined in a reproducible scientific way to have -- to be present or, if present, to have any consequences in clinical outcomes.
MR. DE LA CERDA: All right. I think that's a good break point. It's 12:30.
(Thereupon, a lunch recess was taken from 12:30 p.m. until 1:20 p.m., after which the following proceedings were held:).
Q. (By Mr. De La Cerda) All right. Doctor, we're back on the record. There is one question I wanted to ask you on the degradation issue.
If Prolene's tendency to degrade the human body is clinically significant, clinically relevant

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and statistically significant, should that information be included in the IFUs for the TVT, TVT-O, Gynemesh, Prolift and Prosima?

MR. SNELL: Objection, foundation, form.

Go ahead.

A. Any -- any significant clinical response that deviates from what's reported in randomized control trials should be -- should be a matter of addressing it, regardless if there is a degradation there underneath or not. And there -- there are systems in place that allows for that reporting, more than one system, actually.

Q. (By Mr. De La Cerda) So any risk or complication that's clinically significant, clinically relevant and statistically significant, any risk or complication that's like that should be included in the IFU, do you agree with that?

MR. SNELL: Form, foundation, misstates.

A. If there's -- anything that is clinically significant, statistically significant, let's say we have a voiding dysfunction that is higher than would happen with a Burch procedure, if we have pain, any type of an incidence of urge incontinence or urge incontinence, incidents of any -- that should be

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addressed. If it's different from the RCTs. But if you're going to challenge what's reported on RCTs, then you need to come up with a similar number of patients and you need to have some statistical validity to it.

Q. (By Mr. De La Cerda) Okay. Moving on to a new issue and this one involves TVT and TVT-O.

What does cytotoxicity mean?

A. It means in the -- in experiment, the number of cells that are not viable after exposure to an agent is lower than the expected of the benchmark we established.

Q. The definition you gave me, which, by the way, is very accurate in a certain sense. It's funny, so you told me exactly what the scientific definition is. The other thing I was asking -- that I was thinking in my mind is cytotoxicity, what does that word mean, literally?

MR. SNELL: Form.

A. It means it will -- it means toxicity to the cell.

Q. (By Mr. De La Cerda) Right. And you're aware that the cytotoxicity assessment of the Ulmsten Prolene polypropylene sling, using the ISO

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elution method showed cell lysis and toxicity; correct?

A. There was one other place, and I was able to see that on company documents. There was one other place in which they saw that there was a little cytotoxicity, but when it was -- it could never be reproduced, actually, when it was redone in the agarose, in the agarose form, there was -- in the agarose overlay method, it was not -- it was not cytotoxicity.

And this is significant because the -- when you do a drug elution test, essentially, you're immersing the cells on a pool of this -- of this polypropylene. It will be -- it's a huge amount. It's an amount that you, on purpose, make it -- make it toxic. The toxicity -- the toxicity is -- is supposed to affect a lot more than this.

One of the biggest drawbacks of cytotoxicity assays is that you cannot have a positive control. So when you put agarose on it, you neutralize and you make it more real. You neutralize it and make it more real.

Q. In one of those two testing methods cytotoxicity was shown; right?

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A. It was in one plate. It was not scientifically significant to it. When normal polypropylene was -- was examined on L929 mouse fibroblast cells, there was no cytotoxicity.

Q. Have you studied what happens to tissues when it's exposed to a cytotoxic substance?

A. Yes, I have.

Q. And can you explain what those studies were?

A. Before going to OB/GYN, I did a fellowship on molecular pharmacology, and I did a flow cytometry and cytotoxicity assays, that's what I did every day.

Q. Okay.

A. And we use different agents. So there's -- one thing that we know that tissue configures a protection different from cells. Tissue makes -- makes the viability of cells coming -- mediating by whatever response that you may have to a cytotoxic agent.

So far, and there has not been any evidence that polypropylene is a cytotoxic in the muscle that been by biopsy or by any other -- other test.

Q. Would you agree that necrotized tissue surrounding mesh could lead to erosion or exposure of the mesh?

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A. If you see a necrotic tissue in an incision, it's a wound dehiscence.
Q. So do you agree or disagree with that statement -- or that question?
MR. SNELL: Form.
A. That -- you will have to repeat it. I'm sorry.
Q. (By Mr. De La Cerda) Would you agree that necrotized tissue surrounding the mesh could lead to an erosion or exposure of the mesh?
A. If it's at the wound, yes, it can lead to that.
Q. Should the cytotoxicity assessment of the Ulmsten polypropylene sling showing cytotoxicity be included in the TVT or TVT-O IFUs?
MR. SNELL: Form, misstates.
A. Once you have a pyrogenicity assays and once you have a drug elution and agarose test, if your testing is negative, you just submit it to the FDA. It doesn't have to be included as cytotoxic because it will be -- it will be inaccurate.
Q. (By Mr. De La Cerda) So the answer is no; right?
A. No.

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Q. And what would be your basis for that opinion?
A. My -- the review of the -- the review of the cytotoxicity assays that were made available to me through company documents.
Q. Okay. And which ones were those?
A. The ones on TVT.
Q. And those included the ISO agarose diffusion method?
A. That includes -- there are two types of tests that were done. There was the agarose, the drug elution, and pyrogenicity and to check for the inflammatory reaction also of injected polypropylene.
Q. Any other bases for this opinion?
A. This is -- this is the basis for the opinions.
Q. Do you know what the significance is of mesh being heavyweight as opposed to lightweight?
A. There's -- there's -- the difference -- difference in weight -- in the weight, essentially.
Q. And it's really a description of density, right, not actual mass?
A. It has -- it has to do with how much per a square -- square millimeter is, how much does it weigh

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in terms of grams per square millimeters.
Q. And so do you have an understanding of what the significance in terms of risks and complications --
A. I -- I misspoke.
Q. Okay.
A. I misspoke. It's not per square millimeter. It is per square meter.
Q. Okay.
A. I can double-check that.
Q. Do you have any understanding of what the significance is in terms of risks and complications when you look at lightweight mesh versus heavyweight mesh?
MR. SNELL: Form.
Go ahead.
A. The heavy -- heavyweight meshes with -- not only just with the weight, but with all the other -- the other factors, including fiber size, pore -- pore diameter, and method of coming together, either being knitted or woven, had to do with the tolerability and biocompatibility of the implant.
Q. (By Mr. De La Cerda) So let's get back to my question, though. Is there a difference in terms

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of risks and complications for a patient between lightweight and heavyweight mesh?
MR. SNELL: Form.
A. Not to the point that has been clinically demonstrated.
In theory, we could -- in theory, there is a difference. In the lab, when we use large portions we can infer that, but that has not been shown in the clinical arena of incontinence.
Q. (By Mr. De La Cerda) Okay. So now -- okay.
First of all, let's discuss, what is the theory of the difference -- the theory of the significance as to risks and complications when you compare lightweight versus heavyweight mesh?
A. It's the biomechanical behavior is different. The biomechanical behavior is different not only for that type of preparation, but it's also different for the caliber of the sutures.
In other words, if I use a thinner suture, that being polypropylene or any other material, it will -- it can behave differently. It has a tendency to behave differently than a lightweight mesh or a heavyweight mesh.

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Q. Okay. In what ways?
A. In the testing, when you stretch it, when you fold it, when you place it and have fibroblast growing along the lines of stress of the implant.
Q. Okay. What about in terms of foreign body reaction, is there a difference between lightweight and heavyweight mesh?
A. We used to believe that there was much more on the heavyweight meshes, much more foreign body reaction. But has been found is that that initial reaction of the acute inflammatory -- of the acute inflammatory process and eventually of the chronic inflammatory process leads to the creation of fibroblast.
What biomechanically has been concluded is that that level of stress, the level of stress in these implants, the level of tension or forces that are applied to these implants, behave differently and that seems to determine how fibroblasts grow.
So the heavyweight and the lightweight behave differently. There has not been a single study that shows, at a microscopic level, 80,000, 100,000 samples, but we do have clinical studies that show that number of women. So in terms of the clinical

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behavior, it's probably less difference than what we could see microscopically. In terms of the acute inflammatory reaction, the difference between 200-micron of fiber and a 300-micron fiber is probably not that much.
Q. So do you disagree with the theory that lightweight mesh is safer for patients than heavyweight mesh for use in the pelvic floor?
MR. SNELL: Form.
Go ahead.
A. I think that's a very broad statement to say lightweight meshes for sure are safer. That is a very elementary statement that -- for much more complicated issue.
Q. (By Mr. De La Cerda) Okay. Are you familiar with Closterhofen, Clinga? Are you familiar with Todd Heniford? Are you familiar with these physicians' and scientists' opinions about the safety of lightweight mesh versus heavyweight mesh?
A. I am familiar with their work.
Q. Okay. Do you disagree with their conclusions about lightweight mesh being safer for a patient as compared to heavyweight mesh?
A. I think that their --

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MR. SNELL: Form, foundation.
Go ahead.
A. I think that their conclusions are very, very hypothetical at best.
Q. (By Mr. De La Cerda) Okay. Would you use standard Prolene in the correction of pelvic organ prolapse?
A. We did. Actually, we didn't just use Prolene, we use Mersilene. We used Marlex. We used a variety of materials before this, before we actually use it for slings.
We didn't use it for slings because by the time that midurethral slings came in, we have that 200-micron -- actually 196-micron fiber with a pore size of 1500, and it was -- it was something -- it was something that we knew that would match the thinnest sutures that we could use for a Burch.
Q. To be sure I've got an answer to that particular question, though, the answer is yes, you would use standard Prolene mesh in the surgical correction of pelvic organ prolapse; is that right?
A. Yes.
Q. Okay.
A. I could consider using it. There are other

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factors that may not lead me to use it, but the weight of the mesh is not the only factor.
Q. So you would disagree with anyone that would say that using Prolene mesh in the treatment of pelvic organ prolapse is too dangerous and risky. You disagree with that; right?
A. I would disagree with that, yes.
Q. Have you ever read the deposition of Jorge Holste?
A. I may have read it and if I did, I probably read it over a year ago.
Q. Head of the preclinical department of Ethicon for 30 years, german guy, he opined that Prolene mesh is heavyweight mesh.
Does that ring any bells?
MR. SNELL: Foundation on that one.
A. Prolene mesh, the way they classify is heavy -- heavyweight mesh. There were a number of materials that I'm aware that they work with and they classify according to weight. From the engineering point of view, that might be accurate. From a surgical point of view, there are a lot of other factors that have to be considered.
Q. (By Mr. De La Cerda) Okay. Do you agree

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or disagree that heavyweight mesh causes greater foreign body reaction than lightweight mesh?
MR. SNELL: Form.
A. There might have -- there could be in existence something that says that increases the number of neutrophils, but I have not found any -- any utility on clinical care on predicting the behavior of TVT.
Q. (By Mr. De La Cerda) So do you agree or disagree with that statement?
A. I -- I could not agree or disagree with that. That's so general and I would be speculating on it.
Q. Okay. Do you agree or disagree that leaving less mesh material in the patient's body is important because it will reduce the amount of inflammation and foreign body reaction?
A. That's --
MR. SNELL: Hold on. You have to give me a chance to object.
Overbroad and incomplete hypothetical.
A. That's more than a scientific approach. That's a very attractive approach. And that's -- as surgeons, we don't always base what we do on -- on

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science, but also on common sense backed by science.
And, yeah, if I can take care of something with less mesh, I probably would be attracted to it. On the other side, you need to respect as surgeons that say, "Well, you know, I will use the full-length sling because it has the longest evidence behind it." So in that regard, you're using more material, but you have more evidence behind it.
Q. (By Mr. De La Cerda) Do you agree or disagree that reducing the inflammatory reaction of the body will also reduce the risk of contraction or shrinkage of the mesh?
MR. SNELL: Same objection.
A. We don't -- we don't know that and I could not agree with something that, in general, as a specialty, we don't -- we don't know.
The reduced inflammatory reaction may not work for the best. There's a chain of events that happens during the inflammatory process and that leads ultimately to the creation of a fibroblast angle that is what gives the support beyond the implant.
Q. (By Mr. De La Cerda) It's scarring; right?
A. It is -- it is not a scar. Scar is the most

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simplistic way of looking at it because a scar does not have the same viscoelastic capabilities of tissue. So you have to -- when you say a scar, it's not necessarily a scar in the way that we see scars. It's viscoelastically it's different.
That's why someone can urinate after they have a sling placed and they don't have retention. That's how someone can have normal flows, someone can be continent, at the same time also can go and urinate.
Q. Are you familiar with the term "fibrotic bridging"?
A. I've heard the term "fibrotic bridging," yes.
Q. What's your understanding of that term?
A. It's the growth of a fibroblast from one segment to the next.
Q. Do you agree or disagree that heavyweight meshes induce more fibrotic bridging tissue reaction causing more shrinkage during maturing of the collagenous tissue?
MR. SNELL: Form, foundation.
A. I saw it described at one time. I didn't see anything that could conclude it. I did not see a

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paper that could conclude it. I'm welcome to look at anything that says that fibrotic bridging is significantly more. The first thing I would like to know is how you're going to measure it.
Q. (By Mr. De La Cerda) Okay. So I guess you don't have enough information to either agree or disagree; is that right?
MR. SNELL: Object, misstates.
A. I have -- I have enough information to -- to not agree or disagree with it. And that -- the information that I have is that from one segment to the other, just looking at two segments and the fibroblast that grow between, at one point in time that's not enough to make that conclusion, that fibrotic bridging would cause contraction or anything -- or anything similar like that.
There's -- in one of the papers that I gave, there are two papers that I submitted today about the effect of stress on fibroblast growth, and I think that's more complete than fibrotic bridging.
Q. (By Mr. De La Cerda) So is it fair to say that you disagree with that statement then?
A. I -- I cannot say one way or the other fibrotic bridging. If I would have to commit to

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agreeing or disagreeing with it, I think that fibrotic bridging is, again, very hypothetical -- hypothetical statement. I also believe that I can change my opinion based on what I read.

Q. Okay. So as you sit here today, though, I think -- I think what you're saying, as you sit here today, is you would have to disagree because you believe there's not enough evidence to support the statement? I mean, is that what you're saying?

A. There's not enough evidence to support fibrotic bridging. It's a concept that is interesting. It's a concept that can be studied. It's a concept that has to be taken into the context of what -- how fibroblast grow under stress.

Q. Are you aware that Ethicon's own scientists and consultants have opined that Prolene mesh, the same mesh in the TVT and TVT-O, is heavyweight as opposed to being lightweight?

MR. SNELL: Lacks foundation.

A. I -- I -- I haven't seen the opinion of each one of them.

Q. (By Mr. De La Cerda) Okay. So you're not aware?

A. I'm not aware.

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Q. Should a discussion of whether Prolene mesh is heavyweight be included in the IFUs for the TVT and the TVT-O?

MR. SNELL: Form, foundation.

A. No, I don't think that -- I actually believe that most doctors, if you tell them heavyweight -- about heavyweight and lightweight meshes, they have had to be educated on it.

I know that the great majority of them are probably going to look at me and say, "Okay, Jaime, so you're telling me about heavyweight and lightweight and all these different aspects, tell me how does this translate in the care of my patients?" And I would disagree with -- with any statement that makes anything firm about heavyweights or lightweights because the fact is that the model to a study have not been found.

Q. (By Mr. De La Cerda) Okay. And so your opinion is that it doesn't need to be included in the IFU; right?

A. No, I don't think that has any -- any place in the IFU.

Q. And your basis for that is what? I don't want to put words in your mouth.

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What would be your basis for not having to include it in the IFU?

A. Number one, it's not evidence -- the concept of whatever implications they may have clinically is not evidence-based and, number two, there are no clinical implications that you can attribute to it.

Q. Okay. Part of your report discusses the MSDS. So you've reviewed the MSDS for the raw polypropylene that goes into making the Prolene and the TVT, TVT-O, Gynemesh, Prolift and Prosima?

A. I saw the MSDS about raw -- raw material.

Q. Right. You're familiar with what a Material Safety Data Sheet is?

A. I learned about Material Safety Data Sheet along the lines of this -- of this litigation.

Q. Okay. So you know that the Material Safety Data Sheet states that raw polypropylene is incompatible with strong oxidizers, such as peroxides; correct?

A. I read that in the MSDS.

Q. And as a physician, you know that peroxides are present in the human body; right?

MR. SNELL: Form.

A. I am not aware of anyone measuring the

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levels of peroxide.

Q. (By Mr. De La Cerda) Well, as a physician you know that the human body produces hydrogen peroxide as part of the inflammatory process; right?

A. I just have not seen a quantitative assay of it.

Q. Okay. So you know it happens, you just don't know what quantitatively it amounts to; right?

A. I'm not aware of any quantitative study.

Q. And the implantation of the TVT, TVT-O, Gynemesh, Prolift and Prosima causes an inflammatory process; correct?

A. The inflammatory process being defined as a cellular process.

Q. Should the fact that raw polypropylene that goes into making the Prolene, the TVT, the TVT-O, Gynemesh, Prolift and Prosima is incompatible with peroxides according to the MSDS, should that information be included in the IFU?

MR. SNELL: Form.

A. No, it should not be included and based -- no, it shouldn't be included.

Q. (By Mr. De La Cerda) You already know my next question.

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What's the basis for not including that information?
A. No raw material is being asserted on humans.
Q. Okay. Anything else?
A. No.
Q. Okay. You're also -- you addressed this in your report. You're also aware that the MSDS states: "Polypropylene has been tested in laboratory rats by subcutaneous implantation of disks or powder, local sarcomas were induced at the site of implantation."
Do you recall that verbiage that's from the MSDS?
A. From the MSDS.
Q. What does -- what does that verbiage mean?
A. It's a disk, it's a disk of basically raw polypropylene. And the way I see it is there are two factors to it. Number one, the size and the volume of the polypropylene that's being inserted, in addition to the nature of this polypropylene. I cannot speak about this being even remotely similar to what we use on -- on TVT-O and what we use in Prolene sutures because there is not -- there has been no chromatography, no crystallinity assays, no temperature assays on any of this disk. So I don't

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have that information available.
That being said, you can also consider -- you should also consider the host in which most of the time is Wistar rats, Wistar rats or Himalayan rabbits. I had the opportunity to work with Wistar rats. They have a very, very peculiar immune system.
Q. When there is an indication that a substance can cause cancer in animals, like rats, what does that possibly indicate for humans?
MR. SNELL: Form, speculation.
A. It has very, very little implications unless you are consistently prove that these causes -- causes cancer.
Now, this is -- these are -- it's very important to define that these are two different materials. The raw preparations are different from the preparations used in -- in sutures. They're two different things.
Q. (By Mr. De La Cerda) Chronic inflammation has been linked to cancer; hasn't it?
A. That's -- that's not even a theory. That's a hypothesis, actually.
Q. Okay. If mesh -- strike that.
Ethicon -- I need to go back for just a

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second.
You're aware of no test performed by Ethicon to determine whether the surface cracking or degradation, or whatever you want to call it, that's been -- that is seen under -- under microscope of the mesh, whether it's biofilm or whatever you believe it is, you've never seen a test by Ethicon to determine whether that particular characteristic is clinically significant to patients; right?
A. No, there are only three reports that I'm -- that I'm aware of.
Q. Okay. And you're aware of no test by Ethicon to determine whether the weight of Prolene mesh causes more complications in patients in comparison to lightweight mesh; correct?
MR. SNELL: Form, foundation.
A. There's no -- no basis to generate that -- that study.
Q. (By Mr. De La Cerda) What do you mean by that?
A. No one has come out with the actual question in terms -- in the question on the hypothesis of it or the theory of it.
Q. Okay.

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A. In other words, just because we think that there's a scientific study that we can do doesn't mean that that needs to be done.
Q. Okay. But Ethicon -- Ethicon, itself, hasn't performed that study; right?
A. I -- I am -- I am not familiar with the specific studies that they have performed on that specific area.
Q. You're aware of no study performed by Ethicon to determine whether polypropylene could be linked to cancer; right?
A. I -- I am not familiar of that, but I know about the dog study that -- in which they -- sutures were evaluated at about eight years and there was no -- no reported cancer that I'm aware of.
Q. Okay. You brought one study with you here. I think it was a case report of cancer and polypropylene. What was it? You mentioned it briefly when we were looking through your materials.
A. It is -- the first case reported of a clear cell carcinoma in the surrounding area to the -- to the incision for the midurethral sling.
I also brought the response from two experts to that specific case report.

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Q. What did that study -- did that study have some sort of conclusion about what might be causing that clear cell carcinoma?
A. No, it does not have a conclusion. There's a hypothesis and that's as far as they can get about a hypothesis about inflammation, I believe.
Q. And so that's one discussion of inflammatory process being at least hypothesized as being responsible for this particular cancer; right?
A. Yeah, unfort- -- I don't want to say unfortunately, it's not unfortunate. It's -- this is not an actual study. This is a case report.
Q. Case report.
A. One case report. And as we have gone through so many times today, the overwhelming data -- there are papers that -- there are articles that describe the continued use of polypropylene in midurethral sling with the incidence of cancer in that population or the frequency of cancer in that population being actually zero.
Q. Okay. So then the question about your opinion, should this warning that's included in the MSDS -- or this verbiage that's included in the MSDS regarding the subcutaneous implant of disk or powder

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where local carcinomas were induced at the site of implantation, should that information be included in the IFUs for the TVT, the TVT-O, Gynemesh, Prolift and Prosima?
A. The answer is no, and the basis of that is that is not relevant to the product that is being implanted.
Q. Has -- are you aware of any studies that Ethicon's done comparing the raw polypropylene with the manufactured version that is actually implanted in humans, any test of any kind?
A. Raw -- raw polypropylene is not used in humans. Raw polypropylene is actually not even used on containers. It has very -- it doesn't have an actual use. It's raw material.
Q. And so you're aware of no studies, though, where Ethicon's tested raw polypropylene versus the finished manufactured product of any type; right?
A. No, I'm not familiar with any studies using raw polypropylene.
Q. Okay. Shifting gears a little bit.
You agree that as a scien- -- a scientist or a physician should not go into a research study with a desire to achieve a specific result; correct?

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A. I -- I -- I'll have to read that. If you can be blinded to your study, that would be optimal, but that's not possible in every -- in every design.
Q. So are you saying that a scientist in a re- -- scientist and a physician -- it's okay for that -- strike that.
It's okay for a scientist and a physician to go into a research study with the desire to achieve a specific result?
A. No, I think that the design of the study would actually protect the study from any desire that anyone could have.
Q. So should or should not the scientist and the physician go into a study with the desire to achieve a specific result?
MR. SNELL: Form, overbroad.
A. I don't -- I don't believe that anyone should go into any study hoping or wishing for a specific result. That's not what the methodology of a science is for.
Q. (By Mr. De La Cerda) You agree that a scientist and a physician should not design a research project for medical publication with the specific purpose of a single result; correct?

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MR. SNELL: Form.
A. It's -- there's no science if you are trying to get it or achieve a specific result.
Q. (By Mr. De La Cerda) You can't go into a medical scientific research trying to answer a question with any preconceived biases; right?
MR. SNELL: Form, overbroad.
A. There's -- we -- we have seen that there -- there's some preconceived biases, but they become clearly evident.
Q. (By Mr. De La Cerda) But you shouldn't go in with any preconceived biases, that's what you shouldn't do; right?
A. You don't -- you don't do that as a scientist.
Q. Right. Do you agree it's not ethical for researchers performing clinical trials to be paid if and only if the clinical trials have certain results?
MR. SNELL: Form, overbroad.
Go ahead.
A. I have no basis to judge anyone that has good science, good knowledge, and to be compensated for it.
Q. (By Mr. De La Cerda) No, and I -- well,

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that's excellent, but my question is a little different.

What I'm saying is whether you believe it's ethical for researchers performing clinical trials to be paid if and only if they produce a study with specific results.

MR. SNELL: Same objection.

Q. (By Mr. De La Cerda) So not the fact they're being paid, just the fact they only get paid if you give me these results?

A. Well, it's -- you're going -- if I'm going to acquire a product from you, and I'm going to make an investment on that product, I'm going to pay you based on what you show me with your -- with your product.

Now, you can -- you can actually do that. You can sell me a product that may not perform as I expect, but if I try that product and I see that consistently works in ways that are the same or better as you present it, you can go back and say that was not an issue there.

Q. Okay. So you can go back in time and say it was okay, it wasn't unethical to do that?

A. It's -- you can go back in time and say it's

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not a matter of ethical or not ethical. I know that there was a truth -- a truthful interaction and that what this physician or anyone in that calculating innovation shows me was -- was real, was actually accurate.

Q. Okay. You mean that you can at least agree that that has a potential to create bias, doesn't it, in the study?

A. I -- but you can -- you cannot put that on the person that is trying to bring it in. There has to be a level of -- of understanding and backtracking.

In other words, if you -- and I'm going to allow myself to place an example. If you try to sell me a medical device, I will have a hard time buying it from you. But when -- if you try to sell me a legal product, I might be more attracted to buy from you and I might believe that you may deliver that legal product.

That has nothing to do with science. I deviated into what -- just to illustrate a point just to answer your question.

Q. You're aware, of course, that Ulmsten was the inventor of original TVT; right?

A. Yes.

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Q. And you've seen the Ulmsten and Nilsson studies that Ethicon tauts as long-term support for their TVT line of slings; right?

MR. SNELL: Form.

A. They also wasn't just the inventor of the TVT. At that time he brought the most innovative kind of approach to incontinence. I mean, we -- we were -- until that time, we were doing continence procedures in the urethrovesical junction, we were using sutures, we were placing things under tension, we were using absorbable materials that didn't work long term, materials that were not pliable and they came up and changed the way we were thinking about continence care. Continence care became different because of Ulmsten and Petros.

Q. (By Mr. De La Cerda) Getting back to the question. You've seen the studies that Ethicon touts as support for their TVT line of slings; right? You've seen those, the Ulmsten/Nilsson studies; right?

MR. SNELL: Form.

Go ahead.

A. I've seen the Ulmsten studies, I've seen Nilsson, I've seen Falconer, I've seen Petros.

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Q. (By Mr. De La Cerda) You've seen it in the marketing materials for Ethicon that they frequently site to those studies as being support for the use of their slings; right?

A. For that -- for that specific use, yes.

Q. And you've relied on these studies to support your practice of using the TVT line of products; right?

A. I rely on that and I rely more than that on large studies. And the fact is that it has been reproduced over and over again.

Q. Did Ethicon ever inform you that Professor Ulmsten's company, MedScan, the company that owned the rights to the TVT, was promised $400,000 if and only if it produced a study with the TVT showing certain results?

MR. SNELL: Form.

A. There's my interaction with -- or any surgeon's interaction for that sake at that time, would never get into that.

Q. (By Mr. De La Cerda) So you haven't heard that?

A. No, I -- I saw -- I saw that as one of the claims, through all these documents, but really

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didn't -- didn't matter much to me.
Q. Okay. So that particular fact doesn't matter to you?
A. No.
Q. Okay. Shifting gears a little bit. Should a medical device company put profits above patient safety?
MR. SNELL: Form, speculation.
THE COURT REPORTER: I'm sorry, form --
MR. SNELL: Form, speculation. Put overbroad in there, too.
A. Safety and results bring you profits.
Q. (By Mr. De La Cerda) So is the answer no?
A. No.
Q. Should a medical device company rush a product to market with the primary purpose being to defend its market share?
A. There's -- when you have a good product and you have enough market share, yeah, you want to make sure that you keep it and you keep it with quality.
Q. So the answer is yes to that one?
MR. SNELL: Form.
A. On that one -- on that regard, on the general form of that question, yes.

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Q. (By Mr. De La Cerda) What clinical studies were done of the TVT-O before it was released onto the market?
A. There was -- there were a variety of studies. There was the Mulberry study --
THE COURT REPORTER: The --
THE WITNESS: The Mulberry.
A. -- and there was -- there were cadaver studies, and there were studies on outside-in transobturator slings.
Q. Was one of the studies by de Leval?
A. By Delorme first and then de Leval.
Q. Delorme was outside-in; right?
A. Right.
Q. And then de Leval was inside-out?
A. Right.
Q. De Leval is considered the inventor of the TVT-O; is that right?
A. Yes.
Q. And do you know whether the results of de Leval's clinical studies were included in the application for clearance submitted to the FDA for the TVT-O?
A. I'm not familiar with what was exactly

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submitted. I cannot recall it right now. I can go back and check what was submitted, but I'm not familiar with it.
Q. If he had performed a study, do you believe that that study should have been submitted along with the information about the TVT-O to the FDA?
MR. SNELL: Form, calls for regulatory opinion, outside the regulatory scope.
A. I think it goes to whatever -- whatever the FDA feels that it requires from the company or whatever the company fulfills in its obligations to the FDA.
Q. (By Mr. De La Cerda) How about you as a physician, before you're going to use a product, would you want to know all the clinical studies that are out there about that product before you start implanting it?
A. I actually gave -- I have given testimony today that I trust that the FDA is going to do what's best in that regard.
Q. Do you have any understanding of what the clearance process involves, 510(k) clearance?
A. Yes. I do have an understanding of it.
Q. Do you know whether the FDA requires

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clinical studies before a product is 510(k) cleared?
A. I think that they have made -- I don't think, I'm aware that they have made a decision to put in place a mechanism that works exactly with a 510(k).
Now, am I someone to criticize or favor -- or favor that? I probably could sit in my big chair and decide that, but the reality is that there's people with expertise in regulatory affairs at the FDA and people with expertise on regulatory affairs at Ethicon, and they're the ones that need to come together on that.
Q. I guess the issue that I'm really asking about is what you want to know as a doctor. Before you ever implant a product, do you want to know that if there are clinical studies on that product before you've implanted it, do you want to know what those clinical -- what the findings were of those clinical studies before you implant the product?
A. I'm aware of clinical products and design. I'm aware of these studies, but you can present all these studies and one final part is going to be what the FDA regulatory process comes -- comes and tells me.
Q. What I'm saying, though, is you, as an

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implanting physician, okay, a product is presented to you by a medical device company and there are clinical studies out there that are about this particular product. You're going to want to know all the clinical studies that are out there about that product before you implant it; right?

MR. SNELL: Form, asked and answered.

Go ahead.

A. I want to know -- I want to know the studies and I want to know -- obviously, I want to know more than just the studies. I want to know the biomechanics of it, I want to know all these things. But that's -- ultimately, it comes down to that process between the -- between Ethicon and the FDA.

Q. (By Mr. De La Cerda) Okay.

A. And I'm going to trust the product that comes out from it.

Q. Okay. Let's shift gears a little bit.

You're aware that the IFUs for the Gynemesh, Prolift and Prosima state: "The mesh remains soft and pliable and normal wound healing is not noticeably impaired"; right?

MR. SNELL: Foundation on that.

Do you have that IFU? I'm not sure if you

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made a correct statement across all those IFUs.

Do you mind taking a break?

MR. DE LA CERDA: That's fine. Let's do that.

(Thereupon, a recess was taken from 2:11 p.m. until 2:18 p.m., after which the following proceedings were held:)

Q. (By Mr. De La Cerda) Doctor, just for the sake of showing you, this is the Gynemesh -- sorry, I didn't bring a copy of it -- so that's the Gynemesh IFU. The part that I'm referencing is at the bottom, I think it's the second-to-last sentence. It starts with "the mesh remains pliable."

MR. SNELL: Soft and pliable.

Why don't you ask him to read it just so the record is clear.

MR. DE LA CERDA: Yeah, sure.

Q. (By Mr. De La Cerda) Can you read that, Doctor?

A. "The mesh remains soft and pliable and normal wound healing is not noticeably impaired. The material is not absorbed, nor is subject to degradation or weakening by the action of tissue

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enzymes."

Q. (By Mr. De La Cerda) So that statement is included, of course, in the Gynemesh IFU and the Prolift and Prosima IFUs, which also use Gynemesh; right?

A. Yes.

Q. Now, you're aware that Gynemesh PS is Prolene Soft, except for it's used in the pelvic application as opposed to hernia application; right?

A. It's -- Pro- -- Prolene Soft, yes.

Q. Are you aware that in 2001, Ethicon had in its files a conclusion that Gynemesh PS was too stiff for use in vaginal tissues?

MR. SNELL: Form, foundation.

A. It's -- I read something about that from some investigator, but it was -- it was an opinion about being too stiff. I think it was at the -- at the risk of -- I'm not remembering well or -- I'm not speaking accurately, may have been an investigator's opinion.

Q. (By Mr. De La Cerda) Okay. Are you aware that Ethicon also had in its files a conclusion that Prolene Soft should not be pursued as a mesh used in pelvic floor repair because it was too stiff for use

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in vaginal tissues?

MR. SNELL: Same objection.

A. No, I'm not -- I'm not aware of that and that's not what was eventually done.

Q. (By Mr. De La Cerda) Do you know whether scar contracture around the mesh can occur with the Gynemesh?

A. There's -- there's -- there's this -- again, hypothesis that scar contraction could happen around the mesh. So to that -- to that specific issue, I ask what is the objective measurement of a scar contraction or the mesh contraction. I wanted to see where -- where's the evidence to it?

Because when we repair these -- repair these patients with permanent sutures, when we place polypropylene in the uterosacral ligaments or in the sacrospinous ligament, we didn't see any contraction of those fibers. So where is the evidence? No one could ever bring me evidence of a contraction on the mesh.

Q. Okay. Do you know if that -- if this scar contracture around Gynemesh was a problem that Ethicon engineers were trying to solve?

A. I -- I don't even know if they try to solve

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it because I did not see a problem with contraction.
Q. Okay. So you're also not sure, though, whether Ethicon was trying to solve this problem? You probably don't believe it's a problem. That's what it sounds like you're saying, that it's not a problem, but my question is really are you aware whether Ethicon was trying to solve what it perceived to be a problem with contracture of scar tissue around Gynemesh?
MR. SNELL: Foundation.
A. I don't -- I don't see in which model they would try to solve it.
Q. (By Mr. De La Cerda) Okay. But are you aware if they were trying to solve this or not?
A. No, I'm not aware of them trying to solve contractions of any -- any type, any type of implants.
Q. If scar contracture exists around Gynemesh, would that translate into complications for a patient?
MR. SNELL: Form.
A. More than a complication for a patient. The contraction would just tell me that I have to -- I have to make adjustments in my surgery and that brings a whole new set of variables in my -- in my surgery.
Q. (By Mr. De La Cerda) Do you know whether

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or not physicians were asking Ethicon for a mesh which would be better than Gynemesh on the issue of scar contracture?
A. I -- I believe that there was always the -- the idea that we could always have innovation on the type of implants that we would have. Although Gynemesh had more evidence than any other implant. There was more evidence, there are more papers published on Gynemesh than native tissue for specific compartments. We have that. We all -- we all did have an understanding that there was going to be a progression on the innovation of the product. So if there is a course to do that, that's -- that's something that I think every physician would want to see.
Q. And Ethicon did that -- they did just that, didn't they?
A. They -- they actually invited me and give me -- with other doctors, tell me what -- what this -- what would you like to see in -- in the next generation.
Q. They innovated so well that they even developed a mesh, other than Gynemesh, that they thought was safer than Gynemesh; right?

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MR. SNELL: Actually, hold on. Objection, foundation, misstates company intent.
A. I don't -- I don't think that that's what they concluded, that it was safer. I don't think that there is anyone that actually came and say, "Okay, this is safer," or, "We have more evidence to say that it's safer, but you may have to adjust it," or "It may not contract or they will contract." I don't -- I don't think it got to that point. I think that we had what we had with Gynemesh.
Q. (By Mr. De La Cerda) Okay. Did you ever do a presentation on the benefits of lightweight mesh over heavyweight mesh?
A. I did make presen- -- many presentations on how -- on the benefits of lightweight mesh, and that was a prevailing -- the prevailing thought at that time and I still would make a presentation and say there are some benefits on lightweight mesh. There are -- there's some benefits on having less implant, in having less mesh.
The question is when we have all this -- all these different -- different things that we wish for, how much science do I have behind it? And during those -- those presentations, there's always the

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discussion of: Is this really what we want? Do we want bigger pores? Do we want a lighter -- lightweight meshes? Do we want lighter meshes?
I'm not saying that it's going to be a bad thing. It's probably going to be a good thing, but I don't have the science to back it up.
Q. You mentioned that you did present on some of the benefits of lightweight mesh or using less mesh. What would those benefits be?
A. It's a -- the benefits is that you have less inflammatory response, you have less cellular response, you have a better layout of fibroblast and that's the hypothesis behind all this.
But none of those things that we, as a group, thought as -- as physicians thought that was going to be better, wasn't necessarily going to be better. These were things that were not statements. These were things that we have it here and we have this product and it's worth looking to it and it's worth using it and, you know, if I'm going to have -- use something heavier or something light, I probably go with something light because it's more innovative.
Q. It's a reasonable theory to believe that the lightweight mesh is safer for a patient than the

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heavyweight mesh; right?
A. No. That's not --
MR. SNELL: Lacks foundation.
Go ahead.
A. No. That's not what we can conclude with it. We're not talking -- Gynemesh proved to be safe. Gynemesh proved to be effective. This is a totally different set of considerations, scientifically it's a totally different set of considerations.
Q. (By Mr. De La Cerda) Let's do it this way. What I want to do is work from possibility all the way up to truth. Okay?
Possibility, hypothesis, theory and we'll just say reality or truth. Okay?
Is it possible -- do you agree it's possible that lightweight mesh is safer for patients than heavyweight mesh?
MR. SNELL: Calls for speculation.
A. That's -- that's possible.
Q. (By Mr. De La Cerda) Okay. Now let's take the next step.
Would it be a fair hypothesis that lightweight mesh is safer than heavyweight mesh?
A. That's a hypothesis, period. Not fair, not

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unfair, it's just a hypothesis that we would have to test.
Q. Okay. Is it a fair -- based on what you know, is that a hypothesis that could be confirmed?
A. Well, that's a hypothesis that has much less evidence behind it than -- than using Gynemesh.
Q. The step where you would stop the progression, though, would be a theory. You don't believe there's enough to support the theory that lightweight mesh is safer for patients than heavyweight mesh; is that right?
A. These were -- these were considerations that were entertained not at that time. They still entertain a scientific meeting. It doesn't mean that we're going to go -- go out and start using the lightest weight mesh. It doesn't mean -- because we understand meshes a lot better now as -- as physicians. As surgeons, as scientists, we understand it better.
Now, we knew that what we had would -- would give durability. We knew that what we had would give -- would be a good product to use for reinforcement on augmented repairs. There was -- there was some concept along the lines that were not

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as explored as is being explored now. And based on -- on those concepts that were unexplored, we made inferences on how we would like the next mesh to be.
That doesn't take the fact that what we had behind us was data from Gynemesh.
Q. Do you agree that scar contracture can cause recurrence of prolapse? This is in terms of if scar contracture is happening around Gynemesh, can that cause recurrence of prolapse?
MR. SNELL: Foundation.
A. Are you talking about the same side or opposite side or just in general?
Q. (By Mr. De La Cerda) In general.
A. No, that's not the biggest factor on a recurrence of a prolapse.
Q. I'm just going to go through a little list right here.
Do you agree that scar contracture around Gynemesh can cause pain?
A. Contractions of scarring always have the potential to decrease the pliability of not only a mesh augmented repair but of any -- any repair.
Q. That was actually going to be my next question.

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First of all, the pliability can lead to pain? Like reduced pliability can lead to pain in a patient; is that right?
A. If there's less pliability and there are a number of factors to -- for a repair being less pliable, but if there is less pliability and the tissue is placed under -- under stress, yeah, you would -- you would feel more that it would be more pliable.
Q. Could the scar contracture lead to erosion?
A. No.
Q. How about discomfort during sex?
A. Less, less pliability could make things feel not -- not as soft, not as elastic.
Q. Would you agree that for a mesh to be successfully used for the treatment of pelvic organ prolapse it should be soft and compliant with a woman's vaginal tissues?
A. And that is -- that is an excellent question because I would like to define, which I didn't have to define before in the medical arena, I didn't have to define as much what soft and pliable and elastic is.
I have tried to come to -- to the conclusion that there is a level of the formation of stress that

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is required. You cannot have so much deformation that the prolapse comes out, but you still have to have some firmness to your repair. In other words, you drive your car, you need your shock absorbers to give some give, to give some, but you don't want your shock absorbers to be bouncing all over the place. It would be as uncomfortable as no bouncing at all.

So when I -- when I take my car for a shock absorbers check, they have something that actually measures it and they can adjust it. They can adjust the damper and give. We don't have that in the vagina.

Q. Ethicon certainly never tested that issue; did they?

MR. SNELL: Objection, lacks foundation.

A. The vaginal pliability, I think that there was some papers about designing a device -- there was a paper, actually, Dr. Willy Davila, I believe, was testing a device for vaginal pliability; and that would be very useful in getting an actual number, getting an actual measurement that we can take from.

Q. (By Mr. De La Cerda) Is that something that Ethicon did?

A. No, I think -- I don't think -- I'm not

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aware of Ethicon doing that.

Q. Would you agree that clinically there may be an impact of increased rigidity with any given mesh as it may increase vaginal stiffness post-operatively with a potential to impair sexual function?

A. I -- I misspoke on my last answer. I want to correct that.

When I say Ethicon never -- never did that, I cannot conclude that because I'm not aware if they did or if they didn't, but I'm just -- that's what I'm aware of, that I don't know if they did or didn't.

Q. That's fair.

Let me go back to my question, the next question. Would you agree that clinically there may be an impact of increased rigidity with any given mesh as it may increase vaginal stiffness post-operatively with a potential to impair sexual function?

MR. SNELL: Form, speculation, incomplete hypothetical.

A. There's -- the papers that we have does not -- does not suggest or indicate rigidity. If there is a shrinkage or rigidity, it was not demonstrated on the measurements of total vaginal length. When you measure total vaginal length, not on

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one but in two, three studies with comparing different repairs and native tissue repairs to mesh augmented repairs, the vaginal length stays exactly at the same -- at the same length.

Q. (By Mr. De La Cerda) Should Ethicon's conclusion -- strike that.

Should information about the concerns of physicians and at least some within Ethicon that Gynemesh was too stiff or too rigid for vaginal tissues, should that information be included in the IFU or no?

MR. SNELL: Form, asked and answered.

A. No, I don't think that it needed to be included and the fact is that surgeons have the options of doing augmented repairs or doing -- continue doing native tissue repairs. And they will have whatever concern they may have with one or the other, they have the option of doing one or the other. No one mandated to do a mesh repair or a native tissue repair at a certain time. But if you went by the data and went by the durability and went by the evidence about -- with Gynemesh, you have -- you were empowered with information to decide one way or the other.

Ethicon does not tell surgeons who --

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actually, they never told me, I can tell you that, and they would never tell anyone, "You have to do this repair with this type of material." And I don't think they would include that in the IFU and they would not include that on any communication because it's up to the surgeon to decide that.

Q. (By Mr. De La Cerda) So would that be the basis for why that information is not -- does not need to be included in the IFU, according to your opinion?

A. If the information on the -- on the IFU has to do with the product itself and if there's no evidence of the product performing one way or the other, I would not expect anyone to misrepresent it one way or the other. In other words, I don't -- don't misrepresent it saying that it performs better, don't misrepresent it saying that it performs worse. Just give me what the evidence shows.

Q. Would you agree that any future meshes developed by Ethicon for pelvic organ prolapse should be less rigid than Gynemesh?

A. I don't -- I don't know if it's going to be any development, I don't know if it's -- it's going to be on the same rate of damage. I think that --

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THE COURT REPORTER: On the same?
A. On the same rate of -- on the same rate of -- when I say "rate," on the same elasticity or pliability of Gynemesh.
I don't know if it's going to be the same stiffness or not. I just don't know what they're going to do with the next generation.
Q. But my question is, though, is: If they are going to develop the next generation, do you agree that that next generation should be less rigid than Gynemesh?
MR. SNELL: Objection, foundation.
A. I think we will have to first establish a way of rigidity in -- once in the vagina and not just on the testing that we have, biomechanical testing.
We know that biomechanical testing as accurate and as elaborate and as complicated as it can be, it doesn't always predict the -- the rigidity in the vagina, because we don't know how to measure rigidity in the vagina. We don't know how you're going to measure it.
Q. Let me shift gears a little bit.
Okay. You understand before a medical device can be marketed in the United States, the FDA

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requires that the device receive some level of clearance or approval before that marketing happens; right?
A. Yes.
Q. You're aware that Prolift wasn't cleared for marketing in the United States by the FDA until May 15, 2008; right?
MR. SNELL: Form.
A. There were some -- some dates in there, but I don't have the dates complete.
Q. (By Mr. De La Cerda) You understand that Prolift was marketed in the United States for approximately three years before it received clearance. Do you understand that?
MR. SNELL: Form, foundation.
A. Yeah, it's -- it may have been marketed, yes. I don't -- I don't know -- I cannot give you an accurate answer on that.
Q. (By Mr. De La Cerda) Should the fact that Prolift wasn't cleared for marketing in the United States been included in the Prolift IFUs in place prior to May 15, 2008?
MR. SNELL: Form, foundation, misstates the regulatory --

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A. Marketing -- marketing a device -- marketing a device doesn't mean that you cannot -- you cannot sell it. I don't think it has the relationship of one with the other. If you -- if marketing means someone visited me and giving me a brochure and telling me all these things about the product, I really want to look at the evidence. I will be courteous and I will listen to it, but I will go to -- with the evidence.
And the evidence was, at that time and still today, that -- that the materials used were as good as a native tissue and was more durable.
Q. (By Mr. De La Cerda) So you're telling me that doctors didn't need to know before they put in a Prolift if it hadn't even been cleared by the FDA until May 15, 2008?
MR. SNELL: Same objections.
Q. (By Mr. De La Cerda) Because there were -- there were hundreds, if not thousands, of Prolifts put in before it was ever cleared. Do you understand that?
MR. SNELL: Same foundation, objection.
A. I'm not -- I'm not aware of that specific --
Q. (By Mr. De La Cerda) We can -- we don't even have to have a number. If one was put in

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before it was ever cleared by the FDA, do you think it's okay for a doctor to not know that it wasn't cleared by the FDA before he puts it in to a patient?
MR. SNELL: Same objection.
A. It had a 510(k) approval; correct?
Q. (By Mr. De La Cerda) May 15, 2008. So for three years it didn't.
Have you ever seen the correspondence between Ethicon and the FDA about that clearance issue?
MR. SNELL: Same objection, foundation.
A. I'm not aware of that, no.
Q. (By Mr. De La Cerda) Are you aware of the 510(k) being rejected a couple times?
MR. SNELL: Actually misstates the evidence, foundation as well.
Q. (By Mr. De La Cerda) You haven't seen any of that correspondence?
A. Not -- not on that specific issue, no, I have not seen it.
Q. All right.
A. But if you give it to me, I'll check it out. I'll give an opinion on it. That's -- that's ...

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Q. So let's take the simple fact this product was marketed in the United States before it ever had clearance. Now, before a doctor ever implants the product, do you think it's fair for him not to know that the product he's implanting hasn't even been cleared by the FDA?

MR. SNELL: Same objection, misstates the evidence and the foundation as to the clearance.

A. If it's -- I don't want to give you an opinion on something that I haven't seen.

Q. (By Mr. De La Cerda) As you sit here today, you have not reviewed any of the correspondence between the FDA and Ethicon regarding the clearance of the Prolift under the 510(k) process; right?

A. I -- I know that Prolift was cleared and I know that there was -- the product had been sold. I just don't know the specifics of when was it cleared and the dates as you're referring to.

Q. What I want to try to get at now is, as you sit here today, are you going to provide any opinions about the Prolift and the timing of its clearance and what effect that might have on warnings to doctors?

A. As we sit here today, I cannot give you an

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opinion about something that I have not read.

Q. Okay. And so you know today is my opportunity to question you about this issue. This isn't a new issue, it's been around since 2008. So if you're telling me today that you don't have -- you're not prepared to provide an opinion on that issue, that's great. That sends me down one road.

If you're telling me today that you do have an opinion, then that's why -- then I would like to ask questions about it. But if you're not going to opine -- if you don't intend to opine on the effect of the timing of the clearance of the Prolift through the 510(k) process and that effect on what should be warned or what should be told to doctors about the Prolift, then that's fine and we can move on to the next subject.

A. No, I can -- I can look at those papers and I cannot give you an opinion at this time about papers that I have not seen.

Q. Are those papers in your Reliance List?

A. No, I don't think they're in my Reliance List. If they would be, I would have read it.

THE WITNESS: Oh, you didn't --

MR. DE LA CERDA: I'm actually the nice one.

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Out of all the plaintiff's guys you meet, I'm the nice one.

MR. SPARKS: Hey.

MR. DE LA CERDA: He's a nice one, too.

Q (By Mr. De La Cerda) Let's switch gears a little bit.

Do you agree with the FDA's viewpoint that there is a need for more rigorous studies regarding the safety and efficacy of transvaginal mesh kits?

A. The --

MR. SNELL: Hold on. You said -- can you read that last -- he said transvaginal --

THE COURT REPORTER: Mesh kits.

MR. SNELL: I'm going to object, overbroad, to the extent you're including Prolift midurethral slings.

MR. DE LA CERDA: And I'm not, so I do want to be clear about that.

When I'm using this term "transvaginal mesh kits," it's transvaginal mesh for the correction of pelvic organ prolapse.

So let me go back. Let me read the question one more time.

Q. (By Mr. De La Cerda) Do you agree with

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the FDA's viewpoint that there is a need for more rigorous studies regarding the safety and efficacy of transvaginal mesh kits, meaning transvaginal mesh for the correction of pelvic organ prolapse?

A. No, I disagree with that recommendation.

Q. (By Mr. De La Cerda) Okay. And why is it that you disagree?

A. I disagree because there was a wealth of data on -- on the use of transvaginal mesh that has been determined by more than 400 surgeons -- 400 active surgeons that it was adequate.

The decision of the FDA, with all due respect to the organization or to whoever put the time and put their effort in sitting on that committee, did not -- did not translate on or did not convey the experience of all the surgeons.

Q. Did you ever actually see the FDA's 522 orders that were issued with regard to Gynemesh, Prolift and Prosima?

A. I did -- I did read about those, yes.

Q. Do you know what these orders required of Ethicon?

A. Yes. I -- I read about the requirements and I also read at one time the response of Ethicon to the

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FDA.
Q. That was my next question. Do you know what is it that Ethicon did in response to the 522 orders?
A. They -- they made a statement along the lines of what I just mentioned, that there were studies, not only RCTs, not only -- but also cohort studies that show the benefits in durability, it showed the safety profile, it showed risk and complications, very well delineated in ways that no other repair had been addressed.
Q. Did you also see any information regarding Ethicon's estimate on the cost to have complied with the 522 orders?
A. I did not see the exact cost, but I know that any -- any study is costly.
Q. And Ethicon ultimately decided not to perform what was discussed within the 522 orders; correct?
A. That's -- that's what I -- I -- I saw from the -- from that process, from that specific process.
Q. Ultimately, Ethicon decided to pull those products from the market; right? Prolift and Prosima were pulled from the market; correct?
A. Yes.

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Q. And then Gynemesh, the indication was changed from -- well, I guess before there were two indications, then they changed it to just one. So now the indication for transvaginal implant was removed and now it's just abdominal sacrocolpopexy; is that right?
A. That's correct.
MR. SNELL: I'm going to object. Wait. Wait.
THE WITNESS: Okay.
MR. SNELL: Objection, foundation, misstates the evidence and the clearance.
So go ahead.
Q. (By Mr. De La Cerda) So that's -- is that your understanding of what was done is that Prolift and Prosima were pulled from the market but Gynemesh wasn't, just its indication was changed?
MR. SNELL: I'm going to have to object. I didn't hear "pulled from the market." Same objection, misstates the evidence.
If you take my basis, I'm sure you can get a clean question and answer.
Q. (By Mr. De La Cerda) What I'll do is I'll ask it this way: When Ethicon invented a word

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called "decommercialization" and labeled that as what it did for the Prolift and the Prosima, point is ultimately Prolift and Prosima they stopped selling; right?
MR. SNELL: Form, predicate.
A. Yes.
Q. (By Mr. De La Cerda) Gynemesh they changed the indication; right?
A. That's -- yeah, I became aware of that.
Q. And that avoided Ethicon having to comply with the studies required in the 522 orders; correct?
MR. SNELL: Objection, speculation.
A. I don't agree with that --
Q. (By Mr. De La Cerda) Why not?
A. -- last statement. Because I'm not -- I'm disagreeing on the basis that there's -- they could not continue without doing the 5- -- the 522s. I think that a fair trial of this would have been to at least be on the committee that the FDA had. And there was actually the voice of surgeons saying these are -- this is the evidence and part of the evidence was presented on a communication. It was signed by over 400 surgeons and still that was ignored.
And that has less to do with what Ethicon

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could do, the way I look at it, the way I appreciate it, and more to the fact that the FDA decided no, this is the way it's going to be, 522s or -- or not. So what could they do?
Q. This is an interesting point that's come up in my mind. Why is it that the physicians didn't petition Ethicon to comply with the 522 orders? If the product was so good, why don't the physicians say, "Hey, Ethicon, this stuff is great, do the 522 orders, we know it's going to turn out great, we all win"?
Why was there no petition for Ethicon to do that?
MR. SNELL: Calls for speculation.
A. I -- I don't know. That's exactly -- I'm going to -- I'm going to probably answer it that way because it calls for speculation.
Q. (By Mr. De La Cerda) Ultimately, if the product's great, why didn't Ethicon do the studies?
Have you ever been provided a rationale as to why Ethicon decided not to do the 522 studies?
A. No, there was no -- no rationale and we still cannot find a rationale for that, for not complying with the 522. I think that you can -- you cannot tell a company how they're going to go about

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their -- running their business. Although I would like, yeah, to have that power to tell everyone to run their business, it's not like I'm going to be listened on that. And there are other considerations that they may have.

I can tell you that from a surgeons' perspective, yeah, we could have been compelled -- going along the statement that you just made, we could have been compelled to go to Ethicon and I think that that was conveyed at some point, but there's no -- no way to go about it when you're imposed a 522 just off like that.

And I think that part of it -- just to elab- -- elaborate on that -- part of it was that we saw -- we signed that petition, we signed that letter, we say, "Please reconsider this. Let's find another method to do this. There has to be a better method to do this." And I think ten years from now we're going to look back on this and we're going to say that was an inadequate method. It was too rigid and we have to find other methods to have these devices available to surgeons.

Q. Is it necessarily a bad thing, though, for clinical studies to be required before another

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transvaginal pelvic organ prolapse mesh is put on the market? I mean, is that a bad thing? Isn't that a good thing because it can ensure safety for patients?

MR. SNELL: Form.

A. I could -- let me tell you, I'm -- by now, you know that I have done research in one way or another for 25 years and I sponsor individuals to do research and I believe in research and I believe in evidence.

I can -- I will never be able to say, "Oh, no, we don't need another study." I think that everybody wants another study, but the fact is that are we going to put individuals through a study when we have evidence from -- from before, multiple randomized control trials, how fair is that to do another study with women when we have evidence of how it works?

Q. (By Mr. De La Cerda) Do you know if any of the hospitals that you have privileges at had any Prolift or Prosima devices leftover after Ethicon stopped selling those products?

A. No, that's -- in my -- my hospital, there was -- it was not there. Basically the communication came in and the communication is clear and that was

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it.

Q. What do you mean by the "communication"? Did Ethicon say, "Hey, take it off your shelves"?

A. No, we have a product manager in the operating room and any of us that have -- any surgeon that receives a letter would go and send it right away to the product manager.

Q. And what did the letter say?

A. That's the decommercialization letter.

Q. Okay.

A. And that was it.

Q. And so at the time it was decommercialized did those products then get pulled from the shelves of the hospital?

A. Yeah, that's it, they're in a separate cart and the cart doesn't work anymore. I actually tried to find one a few -- a few months later, I couldn't find it. No, that goes to a facility, gets destroyed, that's it.

Q. Okay. Here's a few statements, I want to see if you agree with them.

Do you agree serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse are not rare?

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A. They are rare.

Q. They are rare?

A. They are rare.

Q. So you disagree with that statement?

A. I disagree with the statement that they are not rare.

Q. Do you agree that there is no evidence that transvaginal repair with mesh provides any added benefit compared to traditional surgery without mesh?

A. That's inaccurate and it's not supported by evidence.

Q. So you disagree with that one?

A. I do.

Q. Do you agree that it's not clear that transvaginal repair with mesh is more effective than traditional non-mesh repair in all patients with pelvic organ prolapse and it may expose patients to greater risk? Do you agree or disagree with that?

A. I disagree with that.

Q. Do you agree that mesh used in transvaginal pelvic organ prolapse repair introduces risks not present in traditional non-mesh surgery for pelvic organ prolapse repair?

A. I -- in a general sense, I disagree with

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that except with a fact that the risk is inherent to the implant only.
Q. Which would be exposure; right?
A. Which would be mesh exposure.
Q. Mesh exposure. Mesh exposure.
Okay. Do you agree mesh placed abdominally for a pelvic organ prolapse repair results in lower rates of mesh complications compared to transvaginal pelvic organ prolapse surgery with mesh?
A. I don't agree -- I don't agree with that. And the basis for my disagreement with it isn't only the clinical -- the clinical evidence, but also my experience.
Q. Do you agree that native tissue repairs have similar outcomes to synthetic mesh without the risks inherent in mesh use?
MR. SNELL: Form, vague.
A. They -- the evidence shows in randomized control trials that native tissue repairs have other -- other risks.
Q. (By Mr. De La Cerda) So you would disagree with this statement; right?
A. Yes, I would.
Q. Do you agree or disagree the native

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tissue -- strike that.
Do you believe it would be a reasonable decision for a doctor to stop using the Prosima device following the July, 2011, FDA warning?
MR. SNELL: Incomplete hypothetical, speculation.
A. I think that there's a -- I mean, I will have to think for all the other surgeons, but I think it's reasonable whenever you have a letter from an organization like the FDA and you -- all of us not being completely -- completely aware of that process on how it came through, it comes as a surprise that we don't have a problem. I think it comes as a surprise not only for us, it comes as a surprise for the patients.
Q. (By Mr. De La Cerda) So it would be reasonable for a doctor to do that?
A. I think it's reasonable for anyone to think that there's something wrong and it requires a lot of reading and a lot of research to really be in tune with the reality.
Q. And so it would also be reasonable for a doctor to stop using the Prolift and the Gynemesh transvaginally after that July, 2011, FDA warning;

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correct?
MR. SNELL: Same objection, speculation, incomplete hypothetical.
A. It's a -- it's reasonable on the basis of human nature.
Q. (By Mr. De La Cerda) At any point after the July, 2011, FDA warning, did you decide to stop using Prosima, Prolift or Gynemesh transvaginally?
A. I think that everyone look at it and everyone stop using it for the wrong reasons, less because of evidence, and more because of the -- of the fear of being involved in litigation, which is real, and being involved in a situation having to explain themselves when there is not a clear -- a clear picture about the reality of it.
Q. But you did stop using Prosima, Prolift and Gynemesh transvaginally at some point after the July, 2011, FDA warning; right?
A. I -- I think I continue using what -- what it did, it did happen is that I communicated, "Listen, we need to take a look at this," but I continued using it.
Q. You continued implanting it?
A. Yes.

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Q. Until they were pulled from the market or stopped, they were stopped selling or decommercialized; right?
A. Yes, once you have -- you have that, I don't -- I don't want to use it.
Q. Do you agree -- do you agree that surgical mesh to repair pelvic organ prolapse is a high-risk device?
A. It's a --
MR. SNELL: Foundation.
Go ahead.
A. It's a game like talking about 522, some 510(k)s, high risk, low risk, it's not -- it's not scientifically accurate.
I do agree that if you're going -- if you're going to use it, you need to be well-trained on it, and you just don't start doing prolapse or continence procedures because a device is easy to use. You still have to be trained and read what's behind all that. That's my opinion of how I run my professional career. It's my -- my profession.
That's how we do it on credentialing in my hospital, that's going to be up to the credentialing institutions and the physicians to decide how much

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training they will -- they will have.
Q. (By Mr. De La Cerda) And so at this point, you can't tell me whether you can label surgical mesh to repair pelvic organ prolapse as high risk; right?
A. Yeah, it's labeled high risk and there's communication from the FDA labeling it high risk. What I -- I can tell you is that the terminology of high risk or low risk brings other implications. If you look at the evidence, I will say, "Well, you know, it's really a risky procedure like any surgery."
Q. And so you're not going to offer testimony that the Gynemesh implanted transvaginally or the Prosima or Prolift are low-risk devices, are you?
MR. SNELL: Objection, misstates his prior testimony.
Go ahead.
A. I will not go with low risk or high risk. I think that whole terminology is so -- is so nonspecific. What's -- if I -- if you compare it to a heart surgery, if you compare it to -- to any other -- an appendectomy, there's always risk. So I cannot classify one way or the other.
There's -- there's -- I believe that there

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is more to that high-risk, low-risk classification than what we can actually explain on the frame of a deposition.
Q. (By Mr. De La Cerda) Do you know whether or not Ethicon did an internal risks analysis to determine risk scores for the pelvic organ prolapse mesh devices? Like whether they were going to -- whether Ethicon was going to label them low, moderate, high risk?
A. I'm not aware of them doing that and actually, there's -- there was an effort, not by Ethicon but by the professional societies to use the Dindo classification and modify it for -- for prolapse. So that's -- that tells you the extent.
The reason why I'm explaining is it tells you the extent of how elaborate the process is. I don't think that Ethicon probably -- I think they were too busy with other things to develop anything, anything like that.
Q. Let's switch gears a little bit here.
Are you okay on breaks?
A. I'm good.
Q. Okay. We are getting close. Okay.
If a synthetic graft product like Prosima

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does not do better than a native tissue repair in terms of safety and efficacy, do you think it should be introduced to the market?
MR. SNELL: Foundation.
Go ahead.
A. The -- the basis for Prosima for any other procedure, they don't do well with whatever benchmark that you use, you need to reconsider, you need -- you have a choice in the market, obviously, but there's -- that's not what we saw with Prosima. The cohort studies done on Prosima follow the experience with Prolift and it showed that it was better than native tissue repairs.
Q. (By Mr. De La Cerda) You're aware that Ethicon was told by some of its top consultants it did not make sense to use the Prosima in people with lesser degrees of prolapse given the outcomes?
A. Any consultant may have an opinion. That's something that -- that's something that Ethicon always foster for anyone to give an opinion. And it's not like we were that shy of giving an opinion because we actually offer plenty of it.
Q. Would you disagree with that -- this particular opinion?

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A. I disagree.
Q. Do you agree or disagree with the following statement: There is no authoritative paper to support that Prosima outcomes are superior or even comparable to colporrhaphy?
A. I disagree with that, and the papers are authoritative and within the context of evidence previously gathered by the use of Gynemesh and Prolift.
Q. So if the primary investigator for the Prosima trial which studied whether or not the product was effective for Grade II and III rectocele and cystoceles made that statement, you would disagree with her?
A. I'm not aware -- are you speaking about Dr. Zyczynski?
Q. I guess ultimately -- you know, what I'll do, I'll just withdraw the question. I think you've already answered anyway.
You disagree with the prior statement, so I think you answered that anyway.
A. I'm going to refer to her on first name because I think that she will be okay with it. Her first name is Halina, H-a-l-i-n-a.

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Q. If the overall consensus of a medical device company's consultants and experts is that it would be a mistake to launch a device on the market, do you think it would be wrongful for the company to launch that device anyway?
A. The --
MR. SNELL: Wait. Hold on. Objection, speculation, incomplete hypothetical.
A. The fact that you are a scientist doesn't always mean that you're going to know marketing. That's -- there's more than one person making those decisions.
Q. (By Mr. De La Cerda) So you don't believe that it would necessarily be wrongful for a company to launch a product under those circumstances; is that right?
MR. SNELL: Same objection.
A. I think there's more than one opinion that needs to be considered, especially in a multicenter study.
Q. If the overall consensus of a medical device company's scientists and experts is that it would be a mistake to launch the device on to a market, do you think that doctors or patients who are provided the

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device should be told the company's scientists and experts think that the device is a mistake?
MR. SNELL: Form, foundation, incomplete hypothetical.
A. Yeah, I don't think that any company is going to tell you, "Yeah, I'm going to release it and it's mistake."
No, the evidence is there and -- and the evidence was so very clear with Prosima. It was presented in modules, it was presented on the number of patients, it was presented in a multicenter study. It had all the qualities of a good cohort study.
Q. (By Mr. De La Cerda) So you don't think that a doctor or -- a doctor who's implanting a Prosima or a patient who's going to receive a Prosima wants to know before that Prosima is put in that at some point the top consultants and experts at the company believe that Prosima was a mistake, they believe it was a reckless product, that they believe if they put the product out on the market they were going to stop working with Ethicon, you don't think any of that information should be provided to doctors or patients?
A. No.

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MR. SNELL: Hold on. You've got to give me a chance.
Form, foundation.
Go ahead.
A. No, it's -- I don't think that's -- that that should be considered. I think that the scientific evidence supersedes whoever feels that it's in so much power to say, "Oh, it's reckless because I say it's reckless."
Well, this is the evidence, this is the scientific evidence, this is the multicenter evidence. If you insist on calling it reckless or giving an irresponsible opinion, which is what it is, then it's up to you, but this is the evidence on this device.
Q. (By Mr. De La Cerda) So Marcus Carey, you know, is the inventor of Prosima; right?
A. Yes.
Q. And you know he received -- he would receive royalties each time the Prosima was sold; right?
MR. SNELL: Foundation.
A. I -- I'm aware that he got paid for his work.
Q. (By Mr. De La Cerda) Do you know how much he got paid?

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A. No.
Q. Do you know he was the lead author on the Prosima study done by Ethicon prior to launch?
A. There was the first one and then there was another study.
Q. Do you know what his success rate was with the Prosima in that first study?
A. It's -- on the -- the first study was around -- above the hymenal ring, I believe it was in the '70s.
Q. What about below? Below the -- I just lost the word. Hymenian, is that what you said?
A. Hymenal ring.
Q. Hymenal ring.
MR. SNELL: Let me caution you. If you have a study, you should pull it out and look at it. He's not asking you to guess. I mean, we have all this stuff here, you can look at it.
THE WITNESS: Okay.
MR. SNELL: I don't know where you have it, but I would assume it's in one of these things.
A. This is it. This is the study.
Q. (By Mr. De La Cerda) Okay. So go back to the question. Do you know what his success rate was

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with the Prosima in his first study?
A. Let me look through it and I'll --
73.9 percent.
Q. And you say that is above or below the hymenal ring?
A. That's about the hymenal ring.
Q. And how about below the hymenal ring?
A. The rest of it.
Q. What do you mean "the rest of it"?
A. The other percentage.
Q. So it's 70/30?
A. Yes, it's 70 -- yes, it's 73.9 versus 20-something. Either one, yeah.
Q. Do you think the fact that he was the inventor of the product introduced bias in that study?
THE WITNESS: Let me point out -- do you see -- you saw that, right?
MR. SNELL: Okay.
A. Please repeat the question.
Q. Sure.
Do you think the fact that he was the inventor of the Prosima introduced bias into that study?
A. No.

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Q. Why not?
A. I have no reason to believe that he would be bias with it.
Q. Do you know whether Ethicon thought there was a fair amount of spin going on regarding Dr. Carey reporting of his clinical data?
A. Fair amount of?
Q. Spin. Have you ever heard that term "spin," spinning the data, spinning the information?
A. No, no.
Q. Like the politicians do?
A. I have no reason to believe that Professor Carey had any deviations from what he would honestly do.
Q. Do you know whether Ethicon believed that Dr. Carey was spinning the data?
A. No. No, I don't -- I'm not aware of that.
Q. The inventor of Prolift, Dr. Cosson, C-o-s-s-o-n --
A. Cosson.
Q. Cosson.
MR. SNELL: Misstates, lacks foundation. You've got the wrong person.
Q (By Mr. De La Cerda) Is he the inventor of

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Prolift?
A. It was a group.
Q. It was a group, right.
A. It was a group.
Q. You've relied on -- have you relied on data and literature published by Dr. Cosson and the TVM group to support your conclusions that Prolift is safe and effective?
MR. SNELL: Same objection.
A. Well, there was a TVM and there was Prolift. And TVM was a precursor, but is different from the product on Prolift.
Q (By Mr. De La Cerda) Okay. Do you know if Dr. Cosson receives royalties for the Prolift or received?
A. No, I don't -- I'm not aware of what he received.
Q. Do you believe that an inventor who receives royalties for selling his invention can be potentially biased when publishing data regarding his invention?
MR. SNELL: Speculation.
A. I don't -- I don't see them being biased. I have no reason to believe that would be the case.
Q. (By Mr. De La Cerda) You're very

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trusting. You're very trusting.
A. This is high caliber -- high-caliber investigators.
Q. Well paid, too.
You're aware that Ethicon had an alternative mesh to Gynemesh PS that they believe would cause fewer compli- -- fewer serious complications at least as early as 2006; right?
MR. SNELL: Foundation, misstates the evidence.
A. Could you please repeat that?
Q. (By Mr. De La Cerda) Sure.
Are you aware that Ethicon had an alternative mesh to Gynemesh PS that they believed would cause fewer complications at least as early as 2006?
MR. SNELL: Same objections.
A. No, I'm not aware of that, any mesh like that, but I'm also aware that there's very low likelihood that there was any evidence strong enough for Prolene polypropylene.
Q. (By Mr. De La Cerda) What do you mean by that?
A. The evidence on Prolene polypropylene, on

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the behavior of the material, it's -- it was well-established by the time Gynemesh PS came in.

Q. So you don't believe it's possible that Ethicon can have evidence that it had a mesh different from Gynemesh that they believe was safer than Gynemesh?

MR. SNELL: Objection, same objection.

A. I believe it's possible to have another mesh. What I don't believe is that the mesh could be based to be safer or with more evidence.

Q. (By Mr. De La Cerda) Okay. I'm going to ask you whether you agree with the following statements.

Do you agree that physicians should be aware -- made aware of all of the significant safety risks associated with the product in the IFU?

MR. SNELL: Objection, asked and answered. I think he's testified three times on this.

A. The -- the risk of the IFU should pertain to the device. There is no place in the IFU to make a more comprehensive guide for incontinence, nor should the IFU replace training, expertise and textbook reading.

Q. (By Mr. De La Cerda) But you agree that

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all significant safety risks associated with the product should be included; right?

MR. SNELL: Objection, misleads prior testimony.

Go ahead.

A. With the -- with the product specifically associated to the device and -- and -- and the mesh.

Q. (By Mr. De La Cerda) Is that a "yes"?

MR. SNELL: Objection, asked and answered.

A. To the device and mesh, yes.

Q. (By Mr. De La Cerda) Okay. Do you agree that a manufacturer of a medical device that would be implanted in a woman's body is required -- actually, strike that.

Do you agree that an IFU should never exclude known hazards or complications?

MR. SNELL: Objection, I think this is all asked and answered. He's given the same opinions numerous times.

Go ahead.

A. The IFU should talk about the things that are inherent to the device. It's -- it's a guide about the device.

Q. (By Mr. De La Cerda) Can't -- is it okay

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for it to exclude known hazards or complications?

MR. SNELL: Form.

Q. (By Mr. De La Cerda) There are circumstances where I think you believe that it can exclude known hazards and complications; right?

MR. SNELL: Same objections.

A. Things that are not at risk to the patient.

Q. (By Mr. De La Cerda) No, I mean -- okay. If it's a known hazard or complication to it that could happen to a patient, should it ever be excluded from an IFU?

MR. SNELL: Same objection.

A. If it's -- if the complication or the side effect is the same as it would happen with a native tissue repair, I believe that it does not have to be included on the IFU.

Q. (By Mr. De La Cerda) Okay. Do native tissue repairs result in chronic foreign body reaction?

A. Yes.

Q. How is that?

A. There's a reaction to sutures. There's the plication of tissue that dehisce. There is the formation of hematomas or granulomas. There are the

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inherent conditions of the host that could cause it, such as atrophy, autoimmune disorders, lichen planus. So there are a number of conditions that can make a native tissue repair not work, not work well or have granulation tissue or have chronic -- chronic inflammation.

Q. Chronic inflammation. Okay.

Do you agree that if a patient undergoes the TVT procedure under general anesthetic, it has the potential to put the patient at increased risk for urinary retention or urethral erosion?

A. No.

Q. And why is that?

A. Initially, the idea was that when you put a midurethral sling, which is tension free, that you have to adjust it so the patient would not be on retention.

It was -- it was later described that that may have been true for previous slings that were used ideally for vesical junction, but not for midurethral slings. Eventually, the data proved that to be correct, because the rate of voiding dysfunction was below 1 percent.

So one of the -- one of the things that that

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experience validated is something that they didn't know, not even the inventor actually knew that, which is that there is some viscoelasticity to the implant itself.

MR. DE LA CERDA: Okay. What I'd like to do now is take a break and review my notes and then --

MR. SNELL: I'm ready for another bathroom break.

MR. DE LA CERDA: We'll go off the record, thank you.

(Thereupon, a recess was taken from 3:24 p.m. until 3:45 p.m., after which the following proceedings were held:)

Q. (By Mr. De La Cerda) Okay. Doctor, we're back on the record.

There was one thing you mentioned that I wanted to make sure was clear. When we were talking about the compensation you had received as a consultant and then we had a discussion about trying to get --

MR. SNELL: I haven't gotten that either.

MR. DE LA CERDA: That's fine. That's fine. Get a better version.

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MR. SNELL: People are running around like on your side, too, like all over the place.

Q. (By Mr. De La Cerda) There was a discussion about trying to get -- there's a spreadsheet that has listed out some of this information and you mentioned, "Well, it might only be money that was allocated for me, but not necessarily money that I made."

Do you remember discussing that? You might not have used the term --

A. Yes.

Q. -- "allocated."

A. Yes, they did their own allocations for what they were going to spend. It was a budget, internal thing from Ethicon, a budget planning. So it could -- my point is that it could say a number -- it would never be higher than that number, but it was -- it could be lower than that.

Q. So the numbers in the spreadsheet may just be what would have been an allocation or a budget for you for that year and it couldn't be higher, but it might be lower?

A. But it might be lower, yes. It cannot be over that number.

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Q. Okay. Okay. And then have you had a chance to review that on your own, that spreadsheet?

A. I saw it before -- before the Cavness trial and I saw it at the Cavness trial.

Q. And are you sure one way or the other whether those numbers are allocated versus real numbers?

A. They're -- I know they're not real numbers because I would have -- I would have remembered that.

Q. Yeah.

A. The number is -- is high, and I don't remember having 1099s that were that high.

Q. Okay. Okay. Have you understood all of my questions today?

A. Yes, sir.

Q. Have you answered them truthfully and to the best of your ability?

A. Absolutely.

Q. Is there any testimony that you would like to go back and change at this point?

A. No.

MR. DE LA CERDA: Okay. I'll pass the witness.

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CROSS-EXAMINATION

BY MR. SNELL:

Q. Doctor, I want to go through some topics and I'm actually going to go in the order that Mr. de la Cerda covered things just to make sure we're all clear on the record here about where you intend to testify and the bases and whatnot.

Do you recall at the beginning of the deposition you were asked by Mr. de la Cerda about that Abbott study where some of the patients didn't return back to the implanting surgeon for care of a complication?

A. Yes.

Q. All right. In formulating your opinions on the devices we've been discussing today, are there studies in databases that have captive audiences that look at treatment over time regardless of whether it's the implanter, explanter, or someone else?

A. No, there's -- one of the -- one of the things that we have with these type of procedures is that there have been tracks on Medicare databases, they -- and we have other -- other -- other databases that I -- and the citations I put, the Kaiser Permanente, that's --

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Q. Why don't we go there because that's what I was going to ask you about. If you turn to page 14 and 15 --
A. Yes, I got it.
Q. -- of your TVT, TVT-O report. Do you identify different database studies that assess reoperation complication management regardless of who actually is doing that surgery?
A. Right.
Q. Okay.
A. The Canadian registry, there is Medicare, and there's Kaiser Permanente.
Q. So -- and did you find those studies to be reliable?
A. That is -- that is reliable.
Q. So let's take the first one that I'm looking at, it's reference No. 45 in your report, Jonsson Funk, J-o-n-s-s-o-n, Funk. It's the nine-year study where the rate of removal for mesh urethrolysis was 3.7 percent.
A. Yes.
Q. Do you have a recollection as to whether that study contained, you know, over a 100,000 patients or --

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A. There was -- I know for a fact it's over 80,000 patients, close to -- close to 100,000 patients. Most importantly, that rate of -- of revision was about 3 percent.
Q. And did you see a similar rate as to about 3 percent in different database studies and other studies like the Cochrane reviews and randomized control trials?
A. Consistently you go from one paper to another to another and it's 3 percent. It's 2 percent on one, 3 percent. The maximum I have seen is 5 percent. But the number that is most consistently repeated is 3 percent. And that's -- that's accurate to cite to the patients.
Q. So in the Abbott study, let me ask you this. Do you recall that it was a case series based on tertiary referral centers by Dr. Karram, who I think plaintiff's counsel mentioned, and a couple other doctors?
A. Yes, there are probably two papers that say patients would not follow through. The first one is about the -- a review about randomized control trials or any follow up in which patients do not show up, they tend to be considered as -- in the group that did

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not respond to therapy, to treatment, or to the intervention.
The second is that paper that you just mentioned, but the overwhelming data is so high in other areas, in other databases that we don't go by specific papers like that.
Q. So the case series, can -- when you formulated your opinions, did you pay attention and put more effort -- more emphasis on higher level data?
A. Not only formulate my opinions. In everything I read, I need -- I need to know what is it that I'm reading. And I put that scale, that bridge, some people see it as a pyramid, some people see it as a list. We know that case series are at the bottom, randomized control trials reviews are on the top.
Q. The first study, the Jonsson Funk study, can you identify, just for the record, how many patients did that involve in the assessment?
A. It's 188,454 eligible women.
Q. And then the other footnotes, 46, 47, 48, and 49, were those also the different databases you mentioned?
A. Right. The Canadian, the Canadian also has good reliability because the Canadian does have -- has

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a tracking because of their socialized system. They have tracking. They are known to be able to track a variety of conditions, and this is just another one that they -- that they are -- they report.
Q. And so I guess my question is: Did you find these database studies from different databases, based on the volume of patients assessed and the methodologies, to be more reliable than a case series in a limited number of patients?
A. Absolutely, besides these are up in the hierarchy.
Q. You were asked some questions about what you did in formulating your opinions and you've talked about and testified that you reviewed the medical literature. I want to make sure we're clear here.
Did you also look at various Ethicon company documents and evaluate them?
A. Yes, I -- I -- I did. I just -- in the order -- in the order that I read them, I -- I read them most remotely. In other words, I -- it has been more time since I read than from this.
Q. Did you specifically identify in your report Ethicon documents on topics that Mr. de la Cerda asked you about, like mechanical cut versus laser cut, and

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degradation and pore size and things like that in your reports?
A. Well, by -- through the -- through my testimony today, I address. There is no way I would have been able to address it if I wouldn't have read it.
Q. I think you testified to this and you can tell me if I'm correct or wrong.
Did you earlier testify that based on all of your analyses and the bases you talked about here today, that you have not identified any characteristics of the mesh that are a safety risk?
A. Yeah, I don't -- I don't think that there are concerns about safety on -- on -- on any of the products that we were using. If I would have thought there were concerns about safety to begin with, I wouldn't have used them.
Q. And besides the medical literature and the high-level data that you have referenced, do you also rely on your clinical experience?
A. There's -- my experience is important, the data is important, and the caliber of the data is important. Not only that, my experience and the experience of the people that I -- that I talk to.

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You see, it's -- in medicine, we still -- we still value very much the experience, the experience of our colleagues, so I use that and I use also the experience of -- my own experience and the experience of those that investigate. People -- people that are extremely talented are looking at studies.
Q. And at the end, though, in formulating your opinions and coming to your final conclusions about the safety and efficacy of Gynemesh PS, Prolift, TVT, TVT-O, did you put more weight into the randomized level on control trials than individual experience or case series?
A. Randomized control trial is what -- what we wish we would have on everything. But once you have a few randomized control trials, you can build up with other -- with the other studies. You cannot just do the reverse, you have to build up on the strongest ones.
Q. You were asked a lot of questions about your opinions on IFUs and you told Mr. de la Cerda various grounds and bases for your opinions and you talked about how you had reviewed IFUs over many years and numerous times.
Let me ask you this. In your professional

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education role, did you teach and cover the IFU with other pelvic surgeons specific to these devices we talked about today?
A. We could -- we could make -- the answer is yes. We could make any presentation and present any slide, but at the end when we're working together in the specimen and they collaborate, it's the IFU, the one that comes out.
And as a -- as a preceptor or as a teacher, you need to know that IFU by -- by steps and know not only what it says, but what it really says in terms of mechanics. That's important for all -- all products.
Q. And how many of the cadaver labs or these labs that you did included covering the IFU with the surgeons?
A. Every single -- every single lab.
Q. How many cadaver labs did you do on these products? Your best estimate is fine.
A. The VCS here did about six cadaver labs locally. We had -- we used to go to Orlando and it was very convenient for me because when I would miss the plane, because I was seeing patients, I would just drive up there, and it's -- and it was six in the max year, maybe eight.

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Q. Would there be just one surgeon at this event or would there be multiple?
A. No, multiple surgeons. There was more than one -- one preceptor.
Q. Do you have an estimate as to the number of pelvic floor surgeons you would have worked with and trained and went through the IFU with?
A. I never -- never saw more than four. And if I will have two, that would be good. We -- we started with the IFU. We would teach the device and after that, one of the opportunities that we have in the cadaver lab is that we could dissect and get an in-depth view of what -- where the devices went by using the IFU. So it was the ultimate test for an IFU and the test is on performance of the procedure.
Q. You were asked questions about TVT and these products and you expressed the opinion that you don't think that the devices rope, curl, degrade, et cetera.
Did you -- so let me -- so with that preface, did you look at the literature to see whether any of the studies in the patients reported a difference or a hypothesis as to a difference as to laser cut versus mechanical cut mesh? Are there any studies that describe it?

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A. There is not -- there are no actual studies that define one way or the other.

There is actually the well-designed randomized control trials, like the TOMUS, which is evaluating midurethral sling, transobturator and retropubic. And what -- in that specific study, which is an excellent study, it's one of the pillars of what we do, it's -- we -- we found out there was no description of one or the other; and I have the impression that both were used and there was never any difference on it.

Q. For the mechanical versus laser cut, do you cover that in-depth in your report on pages 23 through 25?

A. Yes.

Q. Do you have -- is there a TVT-Secur report over there?

A. Yeah.

Q. Do you recall a study by the name -- maybe the first author's name was Neuman that looked at TVT-O versus TVT-Secur and it reported percentages of complications for erosion and dyspareunia and there was a difference seen on dyspareunia which the authors reported may have been to -- may have been due to

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laser cut mesh. Do you recollect that?

A. That's Dr. Menahem Neuman's study. He's in Israel and he study -- he studied TVT-Secur.

Q. What page are you on?

A. That's 44.

Q. And was that the only study that you were -- that you found in your investigation in the clinical application of these products on women that suggested there may be a difference between the two?

A. There's a -- there's another -- another study that Bianchi-Ferraro and on the -- both of them, there are TVT-Os and TVT-Securs compared and there's no difference on them. That's -- this is just -- this is just illustrate that mechanical cut and laser cut, unless you put it on extreme conditions, way beyond the stressors that would be found on the pelvis, there is no significant difference on the behavior.

Q. Page 45 on the Neuman study, you wrote that the authors theorized that the laser cut mesh was to blame for higher dyspareunia, but there is no scientific data confirming that.

A. There is no scientific data and that is just an opinion and that's -- that's what we -- we have to define what's science, what's an opinion. Sometimes

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you see a study that has good science, but then it becomes an opinion at the end.

Q. Do you recall Mr. De al Cerda asking you about a hypothetical that if laser cut mesh was three times stiffer or more stiffer than mechanical cut mesh would it lead to more complications and he may have even mentioned exposure. Do you recall?

A. Yeah, I do recall.

Q. My question to you is: So in that study by Neuman, did the laser cut mesh have a significantly different rate of erosion than the mechanical cut mesh?

A. There's -- the rate of erosions were -- was lower on the Secur. It was zero versus a 1.4 on the TVT-O.

Q. Have you found any reliable, convincing clinical study evidence that, in your mind, establishes that there is a significant difference in laser and mechanical cut mesh when implanted with the TVT devices in women?

A. There has been no study up to now and, obviously, I'm giving you the opinion that I will welcome any study that makes a difference between -- between the two of them.

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The Cochrane database, actually, did not define that. There is no other study that has defined it.

Q. Do you have an opinion as to whether the weight, pore size, and width of the TVT mesh is proper in that device for the treatment of stress urinary incontinence?

A. For which device specifically?

Q. For the TVT, TVT-O devices, do you believe that the mesh is the proper weight, pore size, and width?

A. Yes, and that's -- that's -- that's a mesh that has the evidence behind it.

Q. And when you say "the evidence," are you talking about the various evidence that you put into your reports?

A. Yeah, we have come to the point, even the communication from the FDA, most recent one, just -- just speaks about the standard for continence care being a midurethral sling.

Q. You were asked a question by plaintiff's counsel about the lighter weight mesh and larger pore mesh.

Has any lighter weight or larger pore mesh

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been studied as much or demonstrated to be as useful and safe as the mesh in TVT for the application of stress incontinence?

A. For -- for stress incontinence specifically, there is no other mesh that has been tested to the extent -- actually, there's no other continence procedure material that have been tested to the extent of TVT.

Q. And is that all different types of studies or just randomized control trials?

A. There are all types of studies that -- but predominantly randomized control trials as -- and we're talking about devices for urinary incontinence.

Q. You were asked a lot of questions about degradation. Do you believe that the available data shows that the Prolene mesh degrades?

A. No.

MR. DE LA CERDA: Form.

Q. (By Mr. Snell) And did you review specifically studies referenced by plaintiff's counsel and others, you went and looked for like the Clavé paper, that purportedly raised this issue of degradation?

A. That is one descriptive paper in which we --

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we can actually look at 26 samples of low density. That's 26 samples out of close to over 2 million -- between 2 million and 3 million slings that I don't think you can reliably give any opinion on that and actually, if it would degrade, I would expect it to perform worse, and that's not the evidence that we have.

Q. Is there evidence, long-term data, that shows sustained durability and low complications in your view?

A. Yes. There is data at five years, ten years and now I believe there is data bordering on the 15 years.

Q. And is that data, in your opinion, consistent or inconsistent with the degradation theory?

A. No.

Q. What's that?

A. It's not consistent with the degradation theory. It's actually inconsistent.

Q. In the Clavé study, did you see that besides the fact that a minority of the mesh is -- had this surface cracking on SEM, when they actually did the chemical analytical testing, did those tests

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demonstrate degradation?

A. No, the samples -- the samples were poorly treated to the point that they -- they were not given a good for analysis.

Classically, explant -- explanted tissue -- I'm sorry, explanted graft is not a good -- it's not a good sample to begin with, much less when you put it through -- through spectroscopy, spectroscopy or chromatography and much less through thermal -- thermal changes.

Q. Were there -- in the Clavé paper, did you see that the authors acknowledged that there was no control group to compare?

A. No, that's not a control -- control study. That's barely a descriptive study.

Q. Did you find any of the data that purported to raise this issue of the hypothesis degradation to be reliable?

A. No, I have not seen one yet that proves degradation with any definition that I've been given of degradation.

Q. Mr. de la Cerda asked you about cytotoxicity and your report -- your report, I believe, covers that pretty much in-depth.

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A. Yes.

Q. And you talked with Mr. de la Cerda about the various Ethicon documents and testing you've reviewed and your opinion about the different types and what those studies show or don't show.

A. Yes, I -- I reviewed the -- Ethicon actually ask a third-party lab to do it. It's a third-party lab in Germany and the reports are clear on all the assays.

Q. And I think Mr. de la Cerda asked you to identify, you know, the bases for your opinion for your cytotoxicity opinions and you identified those documents in your analysis.

Let me ask you this. Is the basis for your cytotoxicity opinions also your personal experience on assessing cytotoxicity issues?

MR. DE LA CERDA: Leading.

A. Yeah, well, I assess cytotoxicity with word in science starting to see cytotoxicity in -- in 1985, from 1985 to 1986, that's all I did in the lab. And it's -- I did that -- I actually presented it at a conference on -- on pharmaco -- on molecular pharmacology. And that's -- that's my experience with it.

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Q. (By Mr. Snell) So you have personal experience in cytotoxicity analyses?
A. I have done bench -- I have done bench work on cytotoxicity.
Q. Did you also evaluate the clinical literature on these devices to see whether they documented or raised a phenomenon that you would attribute to cytotoxicity?
A. I went through all these documents and I read the results on each one of them and I -- I'm in a good position to see what -- what the assays show.
Q. In your opinion, is the TVT mesh cytotoxic?
A. No.
Q. You were asked about clinical data that was available before TVT-O -- the TVT-O device was marketed. Do you recall just covering that topic with Mr. de la Cerda?
A. Yes.
Q. Was there data on -- clinical data, clinical studies on the TVT device before TVT-O went to market?
A. There was clinical data, yes.
Q. Is that data relevant, in your opinion, to TVT-O?
A. Yes, it is.

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Q. Is it the same mesh?
A. It's the same implant.
Q. You were asked about the MSDS sheet that you looked at for the raw polypropylene and a statement in it to the effect that the raw polypropylene -- I don't remember the specific, but it had something to do with compatibility.
My question to you is this: Is the TVT compatible with the female human body implanted -- implantation in the pelvis for treatment of stress incontinence?
A. It is biocompatible. It has been demonstrated that it's biocompatible and it has no similarity to raw polypropylene.
Q. That was going to be my next question. Is raw polypropylene implanted in the TVT process -- TVT device?
A. It's a -- it's a different thing. Totally different -- different type of material.
Q. There was a discussion about sarcoma formation in rats when raw polypropylene was implanted in disk or powder form. Do you recall that?
A. Yes.
Q. Is TVT disk or powder form?

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A. No. And TVT has not been as to a sarcoma and there is actual -- actually a publication about it.
Q. I think in your report at page 26 you go through some of the different epidemiologic studies with regard to the polypropylene slings and cancer and sarcoma.
A. On the --
Q. On the --
A. Which one of the reports?
Q. Probably be TVT, TVT-O report, page 26.
A. Yes.
Q. The top paragraph where you state: "The available data does not show any causal links between polypropylene and cancer," and then you have numerous footnote citations.
A. Actually, the evidence is for lack of the carcinogenic.
Q. And as part of Exhibit 11 there is a paper by the lead author Linder where there was over 2,000 midurethral sling patients who were analyzed. I'll just hand it to you. We'll make sure we put it back into Exhibit 11.
A. Yes.

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Q. Is that one of the studies that form the basis of your opinion that the data show noncarcinogenic --
A. The rate of cancer in these patients was reported to be below baseline.
Q. Have you seen any studies utilizing the Prolene polypropylene in any of these devices we discussed today that show a statistically significant elevated risk of sarcoma formation or cancer in women over and above the expected background rate?
A. No.
Q. And in that study by Linder you just mentioned, is it correct that 49 of the 50 patients had cancer already a baseline?
A. Yeah, that's -- that's the only -- it's 2 out of 2,474. That's what makes for .0- -- 08. That's extremely low. That's actually lower than the reported -- one of the cases was an ovarian cancer and that's lower than the reported rate of ovarian cancer.
Q. Let me put that back in Exhibit 11. Make sure we don't lose that.
You were asked questions by Mr. de la Cerda -- I'm going to circle back around to the lighter weight, larger pore mesh theory.

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Do you know whether actually the TVM group evaluated a larger pore, lighter weight mesh in the development of what became Prolift --

MR. DE LA CERDA: Leading.

Q. (By Mr. Snell) -- that was besides Gynemesh PS?

A. They did. They did and it's in my Reliance List. Professor Jack Tanny evaluated the IFUs of different meshes with absorbable components and with large pore size. Their first conclusion and that's non- -- the first conclusion wasn't Dr. -- Professor Berrocal, B-e-r-r-o-c-a-l.

Professor Berrocal's paper in which the statement was clear the TVM group decided that no absorbable meshes were going to be used. And when a combination was used without a partial absorbable partial polypropylene, they decided that the pore size being so large did not work.

Q. Did you see whether or not the surgeons evaluating the different meshes also evaluated a mesh called Vipro?

A. They did. That's exactly what they did.

Q. Is that a large pore, lightweight mesh as well?

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A. Yeah, it's a large -- large pore. You can get pores as high as 5-, 6,000 microns.

Q. Did that mesh demonstrate better efficacy or tolerability than the Gynemesh PS?

A. No, actually it was -- the performance was worse.

Q. You've heard of the mesh Ultrapro, obviously. Mr. de la Cerda talked to you today about presentations concerning the potential benefits of lighter weight or larger pore meshes.

A. Yes.

Q. Does the Ultrapro mesh also have a risk of mesh exposure?

A. We had -- when we say "we," as the surgeons doing these procedures, we expected that it was going to be less mesh exposure. We actually found that it was exactly the same.

Q. And same thing for dyspareunia or pain?

A. Yes.

Q. In your Prolift report -- do you have that handy? Let's go to page 10 and 11.

A. Yes.

Q. Before we actually get to that, let me ask you this.

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Did you see any clinical studies that you found to be reliable that showed that a larger pore or lighter weight mesh than Gynemesh PS was more effective or safer than Gynemesh PS in the Prolift, Prosima or Prolapse application?

A. No, it was -- it remained on a hypothesis. It remained just as a hypothesis and just we -- we all consider at one point that when we we're talking, I'm talking again about the surgeons, the word preceptors and the other surgeons, which one is going to have the longest data behind it and it was polypropylene.

Q. You mentioned earlier, told Mr. de la Cerda, based on your review of the most reliable data that actually the Gynemesh PS and Prolift had a lower risk of wound complications in native tissue. Do you recall that?

A. Yes.

Q. And I think you also testified that based on your analysis, there was a lower rate or risk of vaginal stenosis requiring surgery for the Gynemesh PS compared to native tissue and you mentioned the Carey study?

A. That is correct. That's accurate.

Q. Was that the same Carey study we were

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looking at earlier?

A. Yes.

Q. Do you know where that is? I want to ask you a question about it.

A. That is in the --

Q. My question is: Do you have it over there somewhere? I just want to ask you a question about it.

Oh, here it is.

A. It is the paper before the last one on the top to the left.

Q. So page 1384, does that report and what you referenced in that randomized control trial that there was a higher rate of reoperation for vaginal stenosis in native tissue compared to the mesh?

A. That's correct.

Q. Do you remember Mr. de la Cerda asked you did Ethicon ever test the pliability of the mesh?

A. Yes, I do recall that.

Q. Now, pliability of the mesh, I think you told Mr. de la Cerda, that that could be related to stenosis or pain.

A. Well, it's -- one thing is that the pliability and the other thing is about the

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contraction or shrinkage and what we were talking was along the lines of what mesh contraction or mesh can increase the pliability. Pliability of a tissue or the elasticity of the tissue has more to do with the tissue itself.

Now, the question is, if the mesh could add to this and the answer is every clinical indication of shrinkage or -- or elasticity does not hold the test of clinical evaluation. If there would be a shrinkage, there would be an actual contraction. The vagina would be shorter. And there is no -- there's no study that demonstrates that the vagina is shorter on this -- on all patients that have been repaired with mesh.

We have had instances in which the vagina is shorter with native tissue repair because there's no augmentation with the mesh. So -- and that communication is not just on my opinion, that's part of the communication that was sent to the FDA.

Q. Are you talking about the paper that was endorsed by hundreds of pelvic surgeons?

A. Yes.

Q. At page 10 and 11 of your report you talk about the Cochrane review and then the randomized

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control data do not show a statistically significant difference in de novo dyspareunia, de novo pelvic pain, vaginal pain, change in sexual function, or change in vaginal length or vaginal caliber.

A. That's the latest Cochrane review, that's exactly what it demonstrates.

Q. And did you also assess the randomized control trials to see if that was an accurate statement, specifically for Gynemesh PS and Prolift?

A. Yeah, there's a -- there's an actual -- there's a -- there are randomized control trials and there is the Lowman paper in which mesh is placed transabdominally, sacrospinously on fixations, uterosacral suspensions, anterior/posterior repairs, they were all evaluated for the incidence of dyspareunia.

Q. You mention that the urine analysis was consistent with the findings by Dietz and Maher, who did a systematic review and found no difference in post-operative or de novo dyspareunia or change in sexual function. Do you see that?

A. Yes.

Q. And that citation is number 24?

A. 24.

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Q. Is that a high-level of evidence, a systematic review metanalysis?

A. That is at the highest level.

Q. And is that what your opinions are based upon?

A. Yes.

Q. You were asked questions by Mr. de la Cerda about characterization of mesh as high risk or low risk, and I think you basically disagreed and said you prefer to kind of evaluate it on its own terms. Is that correct or not?

A. I -- I saw the classification of low risk or high risk to be restrictive and the question is if this -- if this procedure is done with mesh have a higher risk over native tissue repairs.

Q. Did he -- I'm sorry, go ahead.

A. And the answer to that is every time we look at that randomized control trial, the answer to that is no.

Q. So my question is this: Have you put in your report and will you be prepared to discuss at trial how Prolift, Prosima, Gynemesh PS comparing risk, whether it's less risky or higher risk than native tissue repair for things that we talked about

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today with Mr. de la Cerda like recurrence, wound complications, pain, change in vaginal shape, length, things like that?

MR. DE LA CERDA: Form.

A. Surgery has risk. Surgery has multiple risk. Surgery for prolapse has specialized risk that we face every single time that we work with mesh or without mesh. We haven't had a mesh now for a few years and patients still having the same kind of complications that they had with the exception of a mesh exposure because there's no mesh.

Incisions still dehisce the same way, incisions still separate, challenges of wound healing are still seen, granulation tissue is still seen, and actually what we're seeing now is a higher rate of hysterectomies with -- with shorter vaginas.

Q. (By Mr. Snell) Do you plan to discuss at trial how the rates and risks with the Gynemesh PS, Prolift, Prosima compare to the rates and risks with native tissue?

MR. DE LA CERDA: Form.

A. Yes.

Q. (By Mr. Snell) For example, in your report, you -- so for your Prolift report, page 9,

you have -- you have multiple studies that show the efficacy of Prolift and Gynemesh PS compared to native tissue. Do you see that?

A. Yes.

Q. Do you plan to talk about the different rates and risks of recurrence for mesh-based repair, particularly I'm focused on Ethicon Gynemesh PS and Prolift, Prosima compared to native tissue.

MR. DE LA CERDA: Form.

A. Yes.

Q. (By Mr. Snell) And do you plan to discuss rates of wound complications, sexual function and dyspareunia for Ethicon's meshes compared to native tissue?

MR. DE LA CERDA: Form.

A. Yes, I plan -- I plan to testify on those.

Q. (By Mr. Snell) And have you evaluated and investigated those issues?

A. I have thoroughly evaluated. I have -- I run randomized control trial after randomized control trial. I have highlighted the areas that I feel are most important and I have summarized them today on my -- on my testimony.

Q. And have you also identified those --

examples of those data in your reports, as well?

A. I am -- I am ready to go on presented on the numbers.

Q. Lastly, Mr. de la Cerda asked you about if you had any plans for further work in the formulation or analysis. Obviously, you're being deposed today and tomorrow and I will represent to you that there are transcripts not yet available for plaintiffs' experts and some of plaintiffs' experts are not being deposed until even after you.

Do you plan to review those transcripts when they're provided to you and assess them?

A. I will -- I will evaluate them. I'll assess them, and I'm looking forward to see the scientific validity of it.

MR. SNELL: Okay. That's all I have.

MR. DE LA CERDA: Nothing further from me.

MR. SNELL: Thank you.

THE COURT REPORTER: Do either of you need a rough draft on this?

MR. SPARKS: Yeah, I put my email on --

MR. DE LA CERDA: Yeah, I'll take one, too.

(Thereupon, the taking of the deposition was concluded at 4:33 p.m.)

CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF BROWARD)

I, JODY L. WARREN, Registered Professional Reporter, Florida Professional Reporter, Notary Public in and for the State of Florida at Large, certify that the witness, JAIME SEPULVEDA, M.D., personally appeared before me on 3/30/16 and was duly sworn by me.

DATED this 11th day of April, 2016.

JODY L. WARREN, RPR, FPR
Notary Public, State of Florida at Large
My Commission Expires 2/28/19
My Commission No. FF 188650

CERTIFICATE OF REPORTER

I, JODY L.WARREN, Registered Professional Reporter, Florida Professional Reporter, certify that I was authorized to and did stenographically report the deposition of JAIME SEPULVEDA, M.D., the witness herein on 3/30/16; that a review of the transcript was requested; that the foregoing pages are a true and complete record of my stenographic notes of the deposition by said witness.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 11th day of April, 2016.

JODY L. WARREN, RPR, FPR
Notary Public, State of Florida at Large

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
JAIME SEPULVEDA, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.
My commission expires:_____

_____
Notary Public

LAWYER'S NOTES

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